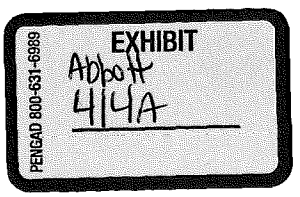
EXHIBIT A

ORIGINAL COMPLAINT

Filed on or About
June 23, 1996



5. For such other and further relief as the Court deems just and equitable.

Further, the Relator, VEN-A-CARE, on its behalf, requests that it receive thirty percent (30%) of the proceeds of this action or settlement of this action collected by the UNITED STATES, plus an amount for reasonable expenses incurred, plus reasonable attorneys' fees and costs of this action.

DEMAND FOR JURY TRIAL

A jury trial is demanded in this case.

Respectfully submitted,

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Florida Bar No. 311227

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ORIGINAL COMPLAINT

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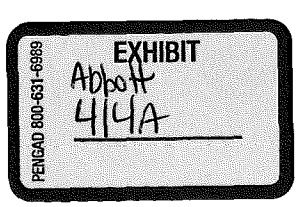

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
SOUTHERN DIVISION

UNITED STATES OF AMERICA Ex Rel. VEN-A-CARE OF THE FLORIDA KEYS, INC. Plaintiff, v. ABBOTT LABORATORIES; [redacted] Defendants.	MAGISTRATE JUDGE GARBER 95-12354 CIV - MARCUS CIVIL ACTION NO. _____ COMPLAINT AND DEMAND FOR JURY TRIAL FILED IN CAMERA AND UNDER SEAL

COMPLAINT
FOR MONEY DAMAGES AND CIVIL PENALTIES UNDER THE FALSE CLAIMS ACT 31 U.S.C. §§3729-3732

COMES NOW, the UNITED STATES OF AMERICA ("UNITED STATES" or "GOVERNMENT"), by and through VEN-A-CARE OF THE FLORIDA KEYS, INC. ("VEN-A-CARE" or "the Relator"), and by the undersigned attorneys on behalf of the UNITED STATES and on the Relator's own behalf and brings this action against ABBOTT LABORATORIES; [redacted]

CASE NO._____

[redacted], (sometimes referred to collectively as, "DEFENDANT DRUG MANUFACTURERS"), and other drug manufacturers not yet joined in this action, for money damages and civil penalties arising out of the DEFENDANT DRUG MANUFACTURERS' violations of the Federal False Claims Act, 31 U.S.C., §§ 3729-3732.

I.

SUMMARY OF THE ACTION

1. This is an action for damages, treble damages, civil penalties and costs against the DEFENDANT DRUG MANUFACTURERS arising from their repeated and knowing reporting of grossly inflated, false and fraudulent cost and price information regarding certain pharmaceutical products specified herein and manufactured and/or sold by them. The false and fraudulent price and cost information was knowingly reported in a manner whereby it was used by the United States Medicare program and by federally funded States' Medicaid Programs in setting reimbursement amounts paid for pharmaceuticals sold by the DEFENDANT DRUG MANUFACTURERS. As a direct and proximate result of the grossly inflated price and cost information reported by the DEFENDANT DRUG MANUFACTURERS, the Medicare and Medicaid programs set allowed charges for pharmaceuticals specified herein of the DEFENDANT DRUG MANUFACTURERS that

were many times greater than the average acquisition costs paid by the providers/suppliers for the drugs that were manufactured and/or distributed by the DEFENDANT DRUG MANUFACTURERS and many times greater than the mark-up over true cost that the Medicare and Medicaid programs intended to pay persons and entities supplying the pharmaceuticals to Medicare and Medicaid beneficiaries. For example, Defendants [redacted] falsely reported price and cost information relating to the drug [redacted] and thus caused the Medicare and Medicaid programs to pay reimbursement amounts for [redacted] which exceeded by approximately 900% a reasonable reimbursement based upon the drug's true average acquisition cost. As a direct and proximate result, the UNITED STATES sustained damages in excess of $300,000,000 for years 1993, 1994, and 1995 to date in the form of federal funds expended for excessive reimbursement for [redacted]. The DEFENDANT DRUG MANUFACTURERS knew or should have known that their false and fraudulent reports of price and cost information would cause the Medicare and State Medicaid programs to pay grossly excessive and unreasonable reimbursement for their pharmaceutical products and that said reimbursement would, in significant part, be paid by the United States Government. The Government has sustained damages in excess of TWO BILLION DOLLARS ($2,000,000,000.00) as a result of the false and fraudulent information knowingly supplied by the DEFENDANT DRUG MANUFACTURERS and other drug manufacturers not yet joined in this action. Accordingly, the United States Government is

entitled to recover treble damages in excess of SIX BILLION DOLLARS ($6,000,000,000), plus civil penalties and costs pursuant to **31 U.S.C. §3729, et. seq.**

II.

THE PARTIES

2. The Plaintiff in this action is the UNITED STATES. At all times material to this civil action, the United States Department of Health and Human Services ("HHS"), The Health Care Financing Administration ("HCFA"), and The Bureau of Program Operations ("BPO") were agencies and instrumentalities of the UNITED STATES and their activities, operations and contracts in administering the Medicare program were paid from UNITED STATES' funds. The UNITED STATES and its subcontractors performing on behalf of the UNITED STATES provided Medicare benefits to qualified beneficiaries which included reimbursement for the pharmaceuticals specified herein manufactured by the DEFENDANT DRUG MANUFACTURERS and relied upon the false and fraudulent price and cost information presented by the DEFENDANT DRUG MANUFACTURERS in setting reimbursement amounts.

3. The States, United States Territories, and the District of Columbia provided Medicaid benefits to qualified beneficiaries which included reimbursement for the pharmaceuticals manufactured by the DEFENDANT DRUG MANUFACTURERS and relied upon the false and fraudulent price and cost information presented by the DEFENDANT DRUG MANUFACTURERS in setting reimbursement amounts. A significant part of said

Medicaid reimbursement was paid from United States Government funds pursuant to **42 U.S.C. § 1396(b).**

4. The Relator, VEN-A-CARE, is a corporation organized under the laws of the State of Florida, with its principal offices in Key West, Florida. The Relator is an infusion pharmacy and provides pharmaceuticals, such as the intravenous and injectable drugs specified in this complaint, as a Medicare Part B supplier and as a Medicaid provider. The Relator has direct and independent knowledge of the information, and is the "original source" of the information on which these allegations are based within the meaning of **31 U.S.C. §3730(e)(4)(A) and (B).** The Relator has standing to bring this action pursuant to **31 U.S.C. §3730(b)(1).** The information upon which these allegations are based was voluntarily provided by the Relator to the Federal Government and States beginning in 1991 and thereafter has been frequently supplemented by the Relator.

5. The Defendant, ABBOTT LABORATORIES ("ABBOTT"), is a corporation organized under the laws of Illinois with its principal offices in Abbott Park, Illinois. At all times material to this civil action, ABBOTT has transacted business in the federal judicial district of the Southern District of Florida by, including but not limited to, selling and distributing pharmaceutical products to purchasers within the Southern District of Florida.

6. [redacted]

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[redacted]

7. [redacted]

8. [redacted]

9. [redacted]

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10. [redacted]

11. [redacted]

12. [redacted]

13. [redacted]

14. [redacted]

15. [redacted]

16. The Defendants specified in paragraphs 5 through 15 are sometimes referred to herein collectively as the "DEFENDANT DRUG MANUFACTURERS". Any and all acts alleged herein to have been committed by each of the DEFENDANT DRUG MANUFACTURERS were committed by said Defendant's officers, directors, employees, or agents who at all times acted on behalf of their respective DEFENDANT DRUG MANUFACTURER.

III.

JURISDICTION & VENUE

17. Jurisdiction is founded upon the **Federal False Claims Act, 31 U.S.C. §3729-32**, specifically **31 U.S.C. §3732**, and also **28 U.S.C. §§1331, 1345**.

18. Venue in the Southern District of Florida is appropriate under **31 U.S.C. §3732(a)** in that each of the DEFENDANT DRUG MANUFACTURERS transacted business in the Southern District of Florida by selling directly or through wholesalers pharmaceutical products in the Southern District of Florida which the respective Defendants knew would be supplied to Medicare and Medicaid beneficiaries and for which the DEFENDANT DRUG MANUFACTURERS knew that grossly excessive and unreasonable reimbursement would be paid to the providers/suppliers by the Medicare and Medicaid programs.

19. A copy of this Complaint and written disclosure of substantially all material evidence and information The Relator possesses have been served on the Government pursuant to **Rule 4(I), Fed.R.Civ.P.**, prior to the filing of this Complaint in camera and under seal by delivering a copy of the summons, Complaint, material evidence and information to the United States Attorney for the Southern District of Florida and by sending a copy of the summons, Complaint, material evidence and information by certified mail to the Attorney General of the United States at Washington, District of Columbia.

20. The Relator alleges, based on information and belief: (A) that no allegation or transaction of defrauding the United States was made prior to the filing of this Complaint

in public disclosures regarding the subject matter herein against any of the DEFENDANT DRUG MANUFACTURERS; (B) that none of the DEFENDANT DRUG MANUFACTURERS was named in public disclosures made prior to the filing of this Complaint regarding the subject matter herein; and (C), if the Court makes a finding against the Relator as to the allegations set forth in (A) and/or (B), that the Relator has direct and independent knowledge of the information on which these allegations are based within the meaning of **31 U.S.C. §3730(e)(4)(A)** and **(B)** and has voluntarily provided the information to the Government before filing this Complaint which is based on the information provided by the Relator to the Government.

IV.

BACKGROUND OF HOW UNITED STATES MONEYS ARE PAID FOR PHARMACEUTICALS UNDER "PART B" OF THE MEDICARE PROGRAM AND THE MEDICAID PROGRAM

21. As one of its functions, HHS, through HCFA, provides health insurance benefits to aged and disabled Americans pursuant to the provisions of the Medicare program, **Title XVIII of the Social Security Act, 42 U.S.C. §1395 et seq**.

22. The Medicare program provides covered health care benefits to certain targeted populations such as those persons who are over age 65, persons who are disabled, and persons who have end stage renal disease ("ESRD").

23. The Medicare program is divided into two distinct parts: (A) Medicare Part A (Hospital Insurance for the Aged and Disabled) covers services and goods furnished by

hospitals, home health agencies, hospices, and skilled nursing facilities; and (B) Medicare Part B (Supplementary Medical Insurance for the Aged and Disabled) covers physician services, and a range of other noninstitutional services, such as durable medical equipment ("DME"), oxygen concentrators, diagnostic laboratory tests, X-rays, and certain limited pharmaceutical products and supplies.

24. The United States Government partially funds state sponsored medical assistance programs for the poor pursuant to **Title XIX of the Social Security Act** through federal matching payments which includes a minimum of fifty percent (50%) for covered prescription drugs. **42 U.S.C. § 1396 et seq**.

25. The States, United States Territories and the District of Columbia are required to implement a State Health Plan containing certain specified minimum criteria for coverage and reimbursement in order to qualify for federal matching funds for Medicaid expenditures. **42 U.S.C. §1396a(a)(30)(A)**.

26. State Health Plans must, in part, provide for reimbursement for prescription drugs pursuant to a formula approved by the Secretary of HHS which determines maximum allowable reimbursement charges as a percentage of the suppliers' estimated Average Acquisition Cost ("AAC") determined for each drug manufactured by each manufacturer whose prescription drugs qualify for Medicaid reimbursement.

27. This case focuses on those pharmaceuticals that are covered under Part B of the Medicare program and under the states' Medicaid programs which are sold and distributed by the DEFENDANT DRUG MANUFACTURERS and for which the Medicare

Part B carriers and states' Medicaid Programs rely on average wholesale price ("AWP") and AAC data reported by the drug manufacturers and distributors in order to establish reimbursement amounts.

28. HCFA administers the Medicare program. HCFA awards cost-reimbursement contracts to private companies to evaluate and to process Medicare beneficiaries' claims for payment on behalf of HCFA. Under Part A, HCFA refers to contractors as "intermediaries". Under Part B, HCFA refers to contractors as "carriers." Under Part B, HCFA pays the carriers to process claims for covered benefits supplied to eligible beneficiaries and to make payments to the suppliers or to the Medicare beneficiaries for the covered services rendered under Medicare Part B. **42 U.S.C. §1395j et seq**.

29. Congress has mandated that Medicare pay no more than eighty percent (80%) of the reasonable charge for Part B pharmaceutical claims from federal funds. **42 U.S.C. §1395(l) et seq**.

30. Part B pharmaceutical claims are submitted in one of two ways. The first is by submitting to the Part B carriers a completed (hard copy) HCFA 1500 Form. The second is through an electronic claims filing procedure whereby the same information required to be included on the hard copy HCFA 1500 Form is transmitted to the Medicare Part B carriers. Two HCFA 1500 Form versions were used during the time relevant to these proceedings. HCFA Form 1500 (1/84) was used by the Medicare program for Part B pharmaceutical claims filed on or after January, 1984. In or about December 1990, HCFA created HCFA Form 1500 (12/90) and required its use for pharmaceutical claims

submitted on or after May 1, 1992. Either HCFA Form 1500 (12/90) or HCFA Form 1500 (1/84) could be used for Part B pharmaceutical claims from December, 1990 through April, 1992.

31. Beneficiaries claims are processed by the carriers as either "assigned", those claims for which payment is made by the carrier directly to the suppler, or "unassigned", those claims for which payment is made by the carrier directly to the beneficiaries.

32. Upon information and belief, the vast majority (in excess of 90%) of pharmaceutical claims are made on an assigned basis.

33. The Medicare program requires its Part B carriers to follow applicable regulations and HCFA guidelines specified in its Medicare Medicare Part B Carriers Manual (HCFA Pub. 15) in determining reasonable reimbursement amounts for covered pharmaceuticals. Part B carriers have determined reimbursement amounts for covered pharmaceuticals at a set percentage over and above the carrier's estimate of the supplier's cost for the pharmaceuticals. (**HCFA Pub. 15, §5202**) The carriers estimate costs on the basis of the AWP of the pharmaceutical.

34. HCFA categorizes Part B covered pharmaceutical drugs by an alphanumeric code and requires its carriers to refer to such pharmaceuticals in this manner.

35. In order to estimate suppliers' costs for specific pharmaceuticals, Medicare Part B Carriers and the State Medicaid programs acquire price and cost information from entities equipped to do specialized data collection of information from which to estimate average wholesale price ("AWP") (the price charged to the supplier purchasing the drug

or supply in question) or average acquisition cost ("AAC") (the supplier's cost in acquiring the drug or supply in question).

36. Medical Economics, Inc. and the Hearst Corporation are nationally recognized companies that specialize in gathering pharmaceutical wholesale and direct price data, and publishing such information in such publications as "The Red Book" which is published by Medical Economics and "The Blue Book" which is published by the Hearst Corporation. The Hearst Corporation also, through its First Data Bank Division, provides an automated data base service containing pharmaceutical price and cost information.

37. The Relator, prior to filing this action conducted certain surveys of (1) the Medicare Part B Carriers; (2) the individual state Medicaid programs; and (3) the entities specified in the preceding paragraph that gather and report pharmaceutical price and cost information. Said surveys established:

a. That the majority of the Medicare Part B Medicare Carriers rely upon price and cost information supplied by Medical Economics ("The Red Book") in setting reimbursement amounts for pharmaceuticals.

b. That more than 90% of the individual state Medicaid programs rely upon price and cost information supplied by the Hearst Corporation's First Data Bank service in setting reimbursement amounts for pharmaceuticals.

c. That Medical Economics, Inc. and The Hearst Corporation both rely solely upon information provided by the DEFENDANT DRUG MANUFACTURERS in reporting AWPs and direct prices for the pharmaceuticals at issue in this cause.

38. HCFA and each State Medicaid program utilize National Drug Codes ("NDC") assigned by the Food and Drug Administration to identify each individual drug for each manufacturer. Estimates of AAC are made for each such NDC coded drug for each manufacturer and separate maximum allowable reimbursement rates are established for each such NDC coded drug.

39. State Medicaid programs follow a similar method to determine AACs for each drug as is followed by the Medicare Part B carriers. Unlike Part B Medicare reimbursement, however, separate maximum allowable reimbursement rates are established for each NDC coded drug.

40. The pharmaceuticals at issue in this civil action are administered intravenously or intramuscularly and are ordinarily sold by the manufacturer or wholesalers directly to specialty infusion pharmacies, such as the Relator, to physicians or outpatient clinics which then supply the drugs and related supplies to the patient. Data regarding AWP and AAC for such pharmaceuticals are collected by Medical Economics and the Hearst Corporation directly from manufacturers, such as the DEFENDANT DRUG MANUFACTURERS.

VI.

THE FRAUD SCHEME PERPETRATED BY THE DEFENDANT DRUG MANUFACTURERS ON THE MEDICARE AND MEDICAID PROGRAMS

41. Beginning on or before June 23, 1989 and continuing to date, each of the DEFENDANT DRUG MANUFACTURERS has knowingly engaged in a fraudulent course of conduct designed to cause the Medicare and Medicaid programs to reimburse providers/suppliers of their pharmaceuticals, including but not limited to those specified in this complaint in amounts that grossly exceed a reasonable reimbursement.

42. Said fraudulent course of conduct entailed intentionally reporting AWPs and AACs on an ongoing basis and failing to provide accurate information regarding AWPs and AACs for pharmaceuticals manufactured, sold and/or distributed by the DEFENDANT DRUG MANUFACTURERS.

43. The false information reported by the DEFENDANT DRUG MANUFACTURERS included AWPs and AACs that exceeded by more than one thousand percent (1,000%) for some drugs the true and correct price charged by the DEFENDANT DRUG MANUFACTURERS to suppliers purchasing the pharmaceuticals directly from the manufacturer or distributor. Such grossly and fraudulently inflated AWP and AAC information caused the Medicare and Medicaid programs to establish reimbursement rates for the pharmaceuticals at issue that grossly exceeded a reasonable reimbursement based upon a reasonably accurate estimate of AWP or AAC.

44. The grossly excessive Medicare and Medicaid reimbursement rates available to suppliers and physicians for the pharmaceuticals in question acted as an inducement to suppliers and physicians to purchase said pharmaceuticals from the manufacturers or distributors who had caused the Medicare and Medicaid programs to establish reimbursement rates enabling the supplier or physician to realize the greatest possible profit over and above the true cost of the pharmaceutical set by the manufacturer or distributor.

45. At all times material to this civil action the DEFENDANT DRUG MANUFACTURERS were well aware that their false reports of AWP and AAC were causing the Medicare and Medicaid programs to establish grossly inflated reimbursement rates for the pharmaceuticals about which the DEFENDANT DRUG MANUFACTURERS provided false information. The DEFENDANT DRUG MANUFACTURERS perpetuated their fraudulent course of conduct for the express purpose of indirectly and directly maximizing their respective economic gains on the pharmaceuticals in question and with the knowledge that fraudulent conduct would cause the Medicare and Medicaid programs to expend federal moneys in the form of grossly excessive and unreasonable reimbursement.

46. The Relator has conducted surveys of the Medicare Part B carriers and the state medicaid programs to determine whether reimbursement amounts for the pharmaceuticals at issue in this action are based upon the price and cost information reported to Medical Economics and the Hearst Corporation by the DEFENDANT DRUG

MANUFACTURERS. Each of the Medicare Part B carriers and state medicaid programs surveyed confirmed that reimbursement amounts set for the pharmaceuticals at issue in this case have, at all times material to this action, been based upon the price and cost information gathered by Medical Economics and the Hearst Corporation.

47. The Relator has conducted an investigation to verify that the Defendants knew or should have known that the price and cost information reported by them about the pharmaceuticals at issue in this case was grossly, falsely and flagrantly inflated. The Relator determined through its investigation that:

a. The DEFENDANT DRUG MANUFACTURERS each reported falsely inflated price and cost information to Medical Economics and the Hearst Corporation about the pharmaceuticals at issue in this case.

b. The true prices charged by the DEFENDANT DRUG MANUFACTURERS for the pharmaceuticals at issue in this case were far less than the false prices reported by the DEFENDANT DRUG MANUFACTURERS.

c. The DEFENDANT DRUG MANUFACTURERS each participated in the Medicaid rebate program mandated by the Omnibus Budget Reconcilliation Act of 1990 ("OBRA '90") and thus were required to pay rebates to the State Medicaid programs based upon their average price for the pharmaceuticals at issue in this case.

d. When reporting average manufacturers' prices for OBRA '90 rebate purposes, the DEFENDANT DRUG MANUFACTURERS reported prices based upon their true sales prices, demonstrating their awareness of their true sales prices. Therefore,

when it benefited the DEFENDANT DRUG MANUFACTURERS to report their true prices to cause the lowest amount of rebate to be paid by them to the states, they used their true prices.

e. When reporting prices to Medical Economics and Hearst Corporation for the pharmaceuticals at issue in this case, the DEFENDANT DRUG MANUFACTURERS falsely reported amounts far in excess of those reported for OBRA '90 rebate purposes. Therefore, when it benefited the DEFENDANT DRUG MANUFACTURERS to report highest prices to maximize the reimbursement amount for the providers/suppliers from the Medicare and Medicaid programs, they used the false and grossly inflated prices.

VII.

THE SPECIFIC FRAUDULENT ACTS AND FALSE STATEMENTS OF DEFENDANT ABBOTT

48. Beginning on or before January 1, 1993 and continuing through the present date, Defendant ABBOTT knowingly and fraudulently caused the Medicare program and the states' Medicaid programs throughout the United States and its territories to pay grossly excessive and unreasonable reimbursement for certain pharmaceuticals manufactured or distributed by Defendant ABBOTT. But for the said actions of Defendant ABBOTT and/or those persons and entities acting directly or indirectly in concert with Defendant ABBOTT, the Medicare and Medicaid programs would not have paid grossly excessive and unreasonable reimbursement for said pharmaceuticals. The actions

committed by Defendant ABBOTT that caused the Medicare and Medicaid programs to pay grossly unreasonable and excessive reimbursement included, but were not necessarily limited to, knowingly and intentionally presenting false and fraudulent price and cost information which Defendant ABBOTT knew would be relied upon by the Medicare and Medicaid programs in setting reimbursement amounts for the pharmaceuticals manufactured or distributed by Defendant ABBOTT.

49. The Relator has not yet determined all of the pharmaceuticals for which the Defendant ABBOTT published false price and cost information and has not yet determined all of the years during which such false information was published. The Relator's investigation has, however, established the specific facts alleged in the following paragraphs with respect to Defendant ABBOTT and the Relator reserves the right to amend this Complaint to add information gathered in the discovery process and through further investigation.

50. Defendant ABBOTT, knowingly and fraudulently published false prices and/or caused Medical Economics ("Red Book") and/or Hearst Corporation ("Blue Book") to publish false average wholesale prices ("AWP") and/or false direct prices ("DP") during, or immediately prior to, the years specified below with respect to the pharmaceuticals specified below. For the purposes of specificity, particularity and clarity, the said false price and cost information has been organized into a chart form for each drug in question and for each NDC Number assigned to each drug in question. The information provided under the columns for Defendant's Published Price, and Red Book and Blue Book "AWP" and

"DP" reflects the false price and cost information provided by the Defendant ABBOTT. The information under the Relator's Cost column reflects the true price that Defendant ABBOTT charged the Relator for the drug or caused another entity to charge the Relator for the drug. As a very small infusion pharmacy, the prices charged to the Relator are equal to or greater than the true average direct price and the true AWP for the drug. The following specific information reflects the false price and cost information knowingly provided by Defendant ABBOTT:

a. DRUG: SODIUM CHLORIDE 0.9%

NDC NO.: 00074158302

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S COST
		"AWP"	"DP"	"AWP"	"DP"	
1993	$8.06			$9.12	$7.68	$1.19
1994	$8.30	$9.57		$9.57	$8.06	$1.10
1995	$8.55	$9.86		$9.86	$8.30	$1.10

NDC NO.: 00074158603

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S COST
		"AWP"	"DP"	"AWP"	"DP"	
1993	$9.90			$11.20	$9.43	$1.19
1994	$10.20	$11.75		$11.76	$9.90	$1.08
1995	$10.51	$12.11		$12.11	$10.20	$1.08

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NDC NO.: 00074798309

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$8.22			$9.29	$7.83	$1.01
1994	$8.47	$9.76		$9.76	$8.22	$1.03
1995	$8.72	$10.05		$10.05	$8.47	$1.03

b. DRUG: LIPOSYN II 10%

NDC NO. 00074979021

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$33.18			$37.53	$31.60	$6.63
1994	$34.18	$39.40		$39.40	$33.18	$6.35
1995	$35.21	$40.59		$40.59	$34.18	$6.35

NDC NO.: 00074979001

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$31.29			$35.39	$29.80	$7.56
1994	$32.23	$37.19		$37.16	$31.29	$6.67
1995	$33.20	$38.27		$38.27	$32.23	$6.68

NDC NO.: 00074979003

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$50.64			$57.27	$48.23	$7.15
1994	$52.16	$57.88		$60.14	$50.64	$6.45
1995	$53.72	$61.94		$61.94	$52.16	$6.46

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c. DRUG: VANCOMYCIN HCL

NDC NO. 00074433201

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$24.72			$27.95	$23.54	$3.75
1994	$25.46	$29.35		$29.36	$24.72	$3.20
1995	$26.48	$30.23		$29.36	$24.72	$3.51

NDC NO. 00074653301

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$49.42			$55.90	$47.07	$7.50
1994	$50.90	$58.68		$58.69	$49.42	$6.40
1995	$52.94	$60.44		$58.69	$49.42	$7.02

d. DRUG: DEXTROSE 5% IN WATER

NDC NO. 00074152203

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$8.16			$9.23	$7.77	$1.20
1994	$8.40	$9.69		$9.69	$8.16	$1.14
1995	$8.65	$9.97		$9.98	$8.40	$1.14

NDC NO. 00074792209

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$9.01			$10.18	$8.58	$1.11
1994	$9.28	$10.69		$10.69	$9.01	$1.12
1995	$9.56	$11.02		$11.02	$9.28	$1.12

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e. DRUG: LIPOSYN II 20%

NDC NO. 00074979101

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S COST
		"AWP"	"DP"	"AWP"	"DP"	
1993	$44.75			$50.61	$42.62	$10.01
1994	$46.09	$53.18		$53.14	$44.75	$9.58
1995	$47.47	$54.73		$54.73	$46.09	$9.58

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NDC NO. 00074979103

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$73.77			$83.43	$70.26	$10.91
1994	$75.98	$84.31		$87.60	$73.77	$10.36
1995	$78.26	$90.23		$90.23	$75.98	$10.36

f. DRUG: LACTATED RINGERS

NDC NO. 00074795309

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$10.30			$11.64	$9.81	$1.27
1994	$10.61	$12.23		$12.23	$10.30	$1.12
1995	$10.93	$12.60		$11.22	$9.45	$1.14

g. DRUG: DEXTROSE 5% WITH SODIUM CHLORIDE 0.9%

NDC NO. 00074794109

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$9.84			$11.12	$9.37	$1.21
1994	$10.14	$11.68		$11.68	$9.84	$1.22
1995	$10.44	$12.04		$12.04	$10.14	$1.23

h. DRUG: DEXTROSE IN WATER 50%

NDC NO. 00074151805

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK "AWP"	RED BOOK "DP"	BLUE BOOK "AWP"	BLUE BOOK "DP"	RELATOR'S COST
1993	$23.46			$26.52	$22.34	$3.12
1994	$24.16	$27.86		$27.85	$23.46	$2.87
1995	$24.88	$28.69		$28.69	$24.16	$2.88

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i. DRUG: DEXTROSE IN WATER 70%

NDC NO. 00074151905

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S COST
		"AWP"	"DP"	"AWP"	"DP"	
1993	$29.05			$32.85	$27.67	$3.75
1994	$29.92	$34.50		$34.49	$29.05	$3.67
1995	$30.82	$35.53		$35.53	$29.92	$3.57

j. DRUG: AMINOSYN II 8.5%

NDC NO. 00074108805

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S COST
		"AWP"	"DP"	"AWP"	"DP"	
1993	$121.85			$137.80	$116.05	$9.17
1994	$125.51	$144.69		$144.69	$121.85	$9.07
1995	$129.28	$149.04		$149.04	$125.51	$9.08

k. DRUG: AMINOSYN II 10%

NDC NO. 00074109005

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S COST
		"AWP"	"DP"	"AWP"	"DP"	
1993	$139.00			$157.20	$132.38	$11.33
1994	$143.17	$165.06		$165.06	$139.00	$11.15
1995	$147.47	$170.01		$170.01	$143.17	$11.15

CASE NO._____

I. DRUG: AMINOSYN II 15%

NDC NO. 00074712207

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S COST
		"AWP"	"DP"	"AWP"	"DP"	
1993	$417.01					$56.13
1994	$429.52	$495.20		$495.18	$417.00	$38.95
1995	$442.41	$510.06		$510.04	$429.59	$38.95

51. As a direct and proximate result of the false price and cost information knowlingly provided by Defendant ABBOTT, as specified in the preceding paragraph, the United States incurred damages in excess of $1,000,000 in the form of grossly excessive and unreasonable reimbursements paid by the Medicare and Medicaid programs for the pharmaceuticals about which the Defendant provided false price and cost information.

VIII.

THE SPECIFIC FRAUDULENT ACTS AND FALSE STATEMENTS OF [redacted]

52. [redacted]

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PAGES 27 THROUGH 59

HAVE BEEN COMPLETELY REDACTED

WHICH INCLUDES THE END OF

PARAGRAPH 52

THROUGH PARAGRAPH 83

XVI.

THE DAMAGE TO THE UNITED STATES CAUSED BY THE FRAUDULENT CONDUCT OF THE DEFENDANT DRUG MANUFACTURERS

84. The Medicare and Medicaid programs reasonably relied upon the false price and cost information knowingly reported by the DEFENDANT DRUG MANUFACTURERS.

85. The Medicare and Medicaid programs' reliance on the false price and cost information was detrimental in that, as a direct and proximate result of said reliance, grossly excessive and unreasonable amounts were paid as reimbursement for the pharmaceuticals of the DEFENDANT DRUG MANUFACTURERS.

86. The Medicare and Medicaid programs intended to establish reimbursement rates based upon an estimate of the average cost of the pharmaceutical to the person or entity supplying the pharmaceutical to beneficiaries.

87. The Relator's cost for each of the pharmaceuticals at issue in this cause represents an amount equal to or greater than the true average acquisition cost of the pharmaceuticals at issue to persons and entities supplying them to Medicare and Medicaid beneficiaries.

88. The false price and cost information knowingly reported by the DEFENDANT DRUG MANUFACTURERS caused the Medicare and Medicaid programs to expend federal dollars which substantially exceeded a reasonable reimbursement for the pharmaceuticals manufactured or distributed by the DEFENDANT DRUG MANUFACTURERS.

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89. The UNITED STATES has sustained damages as the direct and proximate result of the false information reported by the DEFENDANT DRUG MANUFACTURERS equal to the amount of federal dollars expended to pay reimbursements for pharmaceuticals which exceeded a reasonable reimbursement based upon average acquisition costs to suppliers of the pharmaceuticals.

90. By way of example, only, Defendants [redacted] falsely reported price and cost information relating to the drug [redacted] and thus caused the Medicare and Medicaid programs to pay reimbursement amounts for [redacted] which exceeded by approximately 900% a reasonable reimbursement based upon the drug's true average acquisition cost. As a direct and proximate result, the UNITED STATES sustained damages in excess of $300,000,000 for years 1993, 1994, and 1995 to date in the form of federal funds expended for excessive reimbursement for [redacted].

91. The total damages to the UNITED STATES in the form of federal funds expended to pay excessive reimbursement through the Medicare and Medicaid programs as a result of the acts of the DEFENDANT DRUG MANUFACTURERS exceeds $500,000,000 for the years 1993, 1994 and 1995 to date.

92. This action seeks the recovery of all damages sustained by the UNITED STATES during all years as a result of false price and cost information reported by the DEFENDANT DRUG MANUFACTURERS and other drug manufacturers not yet joined as

named defendants in this action for their pharmaceuticals consistent with the specific conduct alleged herein.

93. In the alternative, each of the DEFENDANT DRUG MANUFACTURERS and others not yet charged herein, engaged in a similar course of tortious and fraudulent conduct directed at a common victim, the United States, from on or before June 23, 1989 and continuing to the present date and accordingly each Defendant is jointly and severally liable for the combined amount of damages sustained by the United States as a result of said tortious and fraudulent conduct.

COUNT I

FALSE CLAIMS ACT; CAUSING PRESENTATION OF FRAUDULENT CLAIMS

94. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES, against the Defendants, ABBOTT LABORATORIES; [redacted], under the False Claims Act, **31 U.S.C. §§3729-3732.**

95. Plaintiff realleges and incorporates by reference paragraphs 1 through 93 as if fully set forth herein and further alleges as follows:

CASE NO._____

96. The DEFENDANT DRUG MANUFACTURERS from a date on or before June 23, 1989 to the present date, knowingly [as defined in §3729(b)] caused to be presented to officers or employees of the UNITED STATES GOVERNMENT fraudulent claims [as explained in **United States v. Neifert-White, 390 US 228, 232-233 (1968)**] for payment or approval, in that the DEFENDANT DRUG MANUFACTURERS presented to Hearst Corporation/First Data Bank and Medical Economics, false and fraudulent claims of price and cost information of the DEFENDANT DRUG MANUFACTURERS' pharmaceuticals specified herein, to cause the UNITED STATES to pay out sums of money to the providers and suppliers of the DEFENDANT DRUG MANUFACTURERS' pharmaceuticals grossly in excess of the true costs for obtaining the specified pharmaceuticals from the DEFENDANT DRUG MANUFACTURERS, resulting in great financial loss to the UNITED STATES.

97. Because of the DEFENDANT DRUG MANUFACTURERS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of two (2) billion dollars ($2,000,000,000.00), all in violation of **31 U.S.C. §3729(a)(1)**

COUNT II

FALSE CLAIMS ACT; CAUSING FALSE STATEMENTS TO BE USED TO GET FALSE CLAIMS PAID BY THE GOVERNMENT

98. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES, against the Defendants, ABBOTT LABORATORIES; [redacted]

CASE NO._____

[redacted], under the **False Claims Act, 31 U.S.C. §§3729-3732.**

99. Plaintiff realleges and incorporates by reference paragraphs 1 through 93 as if fully set forth herein and further alleges as follows:

100. The DEFENDANT DRUG MANUFACTURERS, from a date on or before June 23, 1989 to the present date, knowingly [as defined in **§3729(b)**] caused false statements to be used to get false claims [as explained in **United States v. Neifert-White, 390 US 228, 232-233 (1968)**] to be paid by the GOVERNMENT, in that the DEFENDANT DRUG MANUFACTURERS, caused false statements of price and cost information of the DEFENDANT DRUG MANUFACTURERS' pharmaceuticals specified herein to be used by Hearst Corporation/First Data Bank and Medical Economics to get the DEFENDANT DRUG MANUFACTURERS' false claims of price and cost information of their pharmaceuticals specified herein to be paid by the GOVERNMENT to the providers and suppliers of the DEFENDANT DRUG MANUFACTURERS' pharmaceuticals, which claims were grossly in excess of the true costs for obtaining the specified pharmaceuticals from the DEFENDANT DRUG MANUFACTURERS, resulting in great financial loss to the UNITED STATES.

101. Because of the DEFENDANT DRUG MANUFACTURERS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of Two Billion Dollars ($2,000,000,000.00), all in violation of **31 U.S.C. §3729(a)(2)**.

COUNT III

FALSE CLAIMS ACT; CAUSING FALSE STATEMENTS TO BE USED TO CONCEAL AN OBLIGATION TO PAY MONEY TO THE GOVERNMENT

102. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES, against the Defendants, ABBOTT LABORATORIES; [redacted], under the **False Claims Act, 31 U.S.C. §§3729-3732.**

103. Plaintiff realleges and incorporates by reference paragraphs 1 through 93 as if fully set forth herein and further alleges as follows:

104. The DEFENDANT DRUG MANUFACTURERS, from a date on or before June 23, 1989 to the present date, knowingly [as defined in **§3729(b)**] caused false statements to be used to conceal an obligation to pay money to the GOVERNMENT, in that: (1) the DEFENDANT DRUG MANUFACTURERS knew that the UNITED STATES' Medicare program and the States' Medicaid programs were using the DEFENDANT DRUG

MANUFACTURERS' false claims of price and cost information presented to Hearst Corporation/First Data Bank and Medical Economics for purposes of computing formulae of average wholesale price ("AWP") and/or average acquisition costs ("AAC") to pay sums of money to the providers and suppliers of the DEFENDANT DRUG MANUFACTURERS' pharaceuticals for supplying the specified list of pharmaceuticals to Medicare and Medicaid beneficiaries; the DEFENDANT DRUG MANUFACTURERS knew that sums of money paid by the UNITED STATES and State Governments to the providers and suppliers of the DEFENDANT DRUG MANUFACTURERS' pharmaceuticals were grossly in excess of the true costs for obtaining the specified pharmaceuticals from the DEFENDANT DRUG MANUFACTURERS; the DEFENDANT DRUG MANUFACTURERS knew the obligation of the UNITED STATES Medicare Part B carriers and State Governments to recoup governments' funds paid in excess of reasonable costs from the providers and suppliers of the DEFENDANT DRUG MANUFACTURERS' pharamaceuticals; and the DEFENDANT DRUG MANUFACTURERS concealed from the UNITED STATES Medicare Part B carriers and State Governments an obligation of the providers and suppliers of the DEFENDANT DRUG MANUFACTURERS' pharmaceuticals to pay recoupment monies to the UNITED STATES and State Governments, resulting in great financial loss to the UNITED STATES and State Governments.

105. Because of the DEFENDANT DRUG MANUFACTURERS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of Two Billion Dollars ($2,000,000,000.00), all in violation of **31 U.S.C. §3729(a)(7)**.

CASE NO._____

REQUESTS FOR RELIEF

WHEREFORE, Plaintiff, UNITED STATES, demands and requests that judgment be entered in its favor and against Defendants ABBOTT LABORATORIES; [redacted], on Counts I, II and III of the Complaint as follows:

1. On Count I (False Claims Act; Causing Presentation of False Claims) for triple the amount of the UNITED STATES' damages, plus civil penalties of TEN THOUSAND DOLLARS ($10,000.00) for each false claim;

2. On Count II (False Claims Act; Causing False Statements To Be Used To Get False Claims Paid By The GOVERNMENT) for triple the amount of UNITED STATES' damages plus civil penalties of TEN THOUSAND DOLLARS ($10,000.00) for each false statement;

3. On Count III (False Claims Act; causing False Statements To Be Used To conceal An Obligation To Pay Money To The GOVERNMENT) for triple the amount of the UNITED STATES' damages plus civil penalties of TEN THOUSAND DOLLARS ($10,000.00) for each false or fraudulent claim paid;

4. For all fees and costs of this civil action; and

CASE NO._____

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 23d day of June, 1995, I caused an original and a copy of this Complaint to be filed under seal and in camera for sixty (60) days and not to be served on the Defendants named herein until order of this Honorable Court.

I HEREBY CERTIFY that on this 23d day of June, 1995, I caused a copy of this Complaint and written disclosure of substantially all material evidence and information the Relator, VEN-A-CARE possesses to be served on the Government pursuant to Rule 4(i), Fed.R.Civ.P., prior to the filing of this Complaint by delivering a copy of the Summons, Complaint, material evidence and information to the United States Attorney for the Southern District of Florida, and by sending a copy of the Summons, Complaint, material evidence and information by Certified Mail, Return Receipt Requested, to the Attorney General of the United States in Washington, D.C.

Respectfully submitted,

Atlee W. Wampler, III
Florida Bar No. 311227

James J. Breen
Florida Bar No. 297178
WAMPLER, BUCHANAN & BREEN, P.A.
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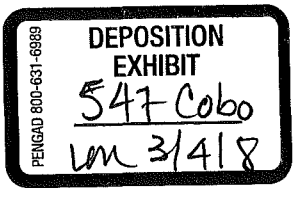
EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Hon. Patti Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc., v. Abbott Laboratories, Inc., CIVIL ACTION NO. 06-11337-PBS	)	(Original Complaint Filed in the Southern District of Florida, Case No. 06-21303-CIV-GOLD/TURNOFF)

THE UNITED STATES' FIRST AMENDED COMPLAINT

The United States brings this fraud action against Abbott Laboratories, Inc. ("Abbott") to recover losses sustained by the Medicare and Medicaid programs. Over the course of several years, Abbott reported inflated pharmaceutical prices that it knew Medicare and Medicaid relied upon to set reimbursement rates for Abbott's pharmaceutical products. Abbott's actual sales prices for its pharmaceutical products were far less than the prices reported by Abbott. By knowingly reporting inflated prices – often 1000% higher than Abbott's actual prices – Abbott ensured its customers received inflated reimbursement and profits from Medicare and Medicaid. Abbott then used the public fisc as a marketing tool, actively promoting government-funded "spreads" between (1) its fraudulently inflated prices and (2) its actual sales prices as an inducement to its customers. In addition, Abbott operated its own home infusion pharmacies and entered into profit-sharing partnerships with health care providers that allowed Abbott to directly profit off Abbott's manipulation of third party reimbursements for its drugs. These efforts allowed Abbott to increase its profits by boosting sales for its drugs.



I. NATURE OF ACTION

1. The United States brings this action to recover treble damages and civil penalties under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33, and to recover damages and other monetary relief under the common law or equitable theories of fraud and unjust enrichment.

2. The United States bases its claims on Abbott having **submitted and** caused the submission of false or fraudulent claims to the United States in violation of 31 U.S.C. § 3729(a)(1), and having made and used false statements to get false or fraudulent claims paid by the United States in violation of 31 U.S.C. § 3729(a)(2).

3. Within the time frames detailed below, Abbott engaged in a fraudulent scheme that caused the Medicare and Medicaid programs to pay excessive reimbursement to Abbott's customers, *e.g.*, pharmacies, physicians, hospitals, home health agencies, nursing homes, home infusion companies, clinics and physicians (hereafter referred to collectively as "Customers"). In furtherance of this scheme, Abbott reported false, fraudulent and inflated drug prices for certain drugs (listed in ¶¶ 30 and 34 below) to several price reporting compendia that the Medicare and Medicaid programs relied upon to set reimbursement rates for Abbott's customers. A chart setting out examples showing the difference between the prices at which Abbott actually sold its drugs and the false prices reported by Abbott is attached hereto as **Exhibit 1**. Abbott knew that the Medicare and Medicaid programs relied on Abbott's reported prices to those compendia to set reimbursement rates for claims submitted for Abbott's drugs. Abbott then sold the drugs for far lower prices, and marketed to existing and potential Customers the government-funded

"spread" between the inflated reimbursement amounts and the actual acquisition costs of the drugs to boost its sales and profits.

4. Abbott knew that its false price reporting and marketing efforts would cause its Customers to submit claims for fraudulently inflated Medicaid and Medicare reimbursement.

5. Abbott's fraudulent scheme to induce Customers to purchase its products by ensuring that federal reimbursement rates for those products would be set at artificially inflated levels violated the FCA, the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), common law and numerous state laws.

6. To get fraudulent claims paid by the United States, Abbott also routinely made false statements directly to state Medicaid programs by reporting these same fraudulently inflated prices to the states. These statements violated the FCA, common law and various state laws.

7. The United States timely asserts the causes of action alleged herein based on the filing of relator's complaint in this action.

II. JURISDICTION

8. The United States' original Complaint in this matter was filed on March 16, 2006 in the Southern District of Florida.[1] The case was transferred to Multi-District Litigation ("MDL") No. 1456 on July 27, 2006. The Court has subject matter jurisdiction to entertain this action under 28 U.S.C. §§ 1331 and 1345 and supplemental jurisdiction to entertain the common law and equitable causes of action pursuant to 28 U.S.C. § 1367(a). The Court may exercise

[1] This case originated in the Southern District of Florida as Case No. 06-21303-CIV-GOLD/TURNOFF. The United States understands that this matter will be transferred back to the Southern District of Florida for trial upon the completion of these MDL proceedings.

personal jurisdiction over Abbott pursuant to 31 U.S.C. § 3732(a) because Abbott resides or transacts business in the District of Massachusetts.

III. VENUE

9. Venue is proper in the District of Massachusetts under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Abbott resides or transacts business in this District.[2]

IV. PARTIES

10. The United States brings this action on behalf of the Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid Services ("CMS") (formerly known as the Health Care Financing Administration), which administer the Medicare and Medicaid programs.

11. Relator Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care"), is a corporation organized under the laws of Florida, with its principal offices in Key West, Florida. Ven-A-Care is a pharmacy licensed to provide the prescription drugs specified in this Complaint and has been, during the relevant period of this Complaint, a Medicare and Florida Medicaid provider. Ven-A-Care's principal officers and directors have included John M. Lockwood, M.D., Zachary Bentley, Luis Cobo and T. Mark Jones, who are each citizens of the United States and reside in Key West, Florida. The FCA, 31 U.S.C. § 3730(b)(1), provides that private parties may bring a lawsuit on behalf of the United States to recover damages for false claims. Ven-A-Care brought this action against Abbott on behalf of itself and the United States.

---

[2] Abbott also resides or transacts business in the Southern District of Florida as well. Thus, venue is also proper in that District.

12. Defendant Abbott is a corporation organized under the laws of Illinois with its principal offices in Abbott Park, Illinois. At all times material to this civil action, Abbott has transacted business throughout the United States, selling and distributing its drugs, including but not limited to those identified in this Complaint, to purchasers within this District.

V. THE LAW

A. The False Claims Act

13. The FCA provides in pertinent part, that:

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government
>
> * * *
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .
> (b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729.

14. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the civil penalties were adjusted to $5,500 to $11,000 for violations occurring on or after September 29, 1999.

B. The Federal Anti-Kickback Statute

15. Congress first enacted the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), in 1972 to protect the integrity of Medicare and Medicaid. Congress strengthened the statute in 1977, and again in 1987, to ensure that kickbacks masquerading as legitimate transactions would not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

16. The anti-kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally-funded medical items, including items provided under Medicare and Medicaid. In pertinent part, the statute provides:

> (b) Illegal remuneration
>
> > (1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind –
> >
> > > (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > > (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment

> > > may be made in whole or in part under a Federal health care program,
> >
> > shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
> >
> > (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person --
> >
> > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b). Those who violate the statute also are subject to exclusion from participation in federal health care programs and, effective August 6, 1997, civil monetary penalties of up to $50,000 per violation and up to three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

VI. THE FEDERAL HEALTHCARE PROGRAMS

17. Medicaid and Medicare were created to provide access to healthcare for elderly, indigent or disabled residents of the United States.

A. The Medicaid Program

18. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled.

19. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. 42 U.S.C. § 1396a.

20. The federal portion of states' Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least 50%, and as high as 83%.

21. The Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A).

22. The Medicaid programs of all states reimburse for prescription drugs.

23. The vast majority of states award contracts to private companies to evaluate and process Medicaid recipients' claims for payment. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid program, which in turn obtains federal funds from the United States.

24. By becoming a participating supplier in Medicaid, suppliers agree to abide by all laws, regulations, and procedures applicable to that program, including those governing reimbursement.

B. The Medicare Program

25. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for the costs of certain healthcare services and items. Entitlement to Medicare is based on age, disability or affliction with end-stage renal disease. 42 U.S.C. §§ 426-426a, 1395o.

26. HHS is responsible for the administration and supervision of the Medicare program. CMS is an agency of HHS and directly administers the Medicare program. The Medicare program has several parts, including Medicare Part B ("Supplementary Medical Insurance for the Aged and Disabled"), which covers physician services, as well as durable medical equipment ("DME") and certain drug products and supplies. 42 U.S.C. § 1395k; 42 C.F.R. § 410.10.

27. Medicare Part B generally covers drugs which are provided either: (a) incident to a physician's service and cannot usually be self-administered (42 C.F.R. § 410.26 (*e.g.*, certain oncology drugs)); or (b) in conjunction with the medical necessity of an infusion pump or nebulizer or other DME device payable under Medicare's DME benefit. 42 C.F.R. §§ 405.517, 414.701.

28. During the relevant time period, CMS contracted with private insurance carriers ("Contractors") to administer and pay Part B claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. In this capacity, the Contractors act on behalf of CMS. 42 C.F.R. § 421.5(b).

29. Contractors receive, process and pay claims under Medicare Part B for drugs from various Medicare providers and suppliers. Typically, once a contractor approves a claim, the contractor then submits a payment request to a Medicare bank account funded by federal funds.

C. Drug Reimbursement Under Medicaid and Medicare

30. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-97, requires pharmaceutical companies to submit to the Food and Drug Administration ("FDA") a listing of every drug product in commercial distribution. 21 U.S.C. § 355. The FDA provides for the assignment to each listed drug product of a unique 11-digit, 3-segment number, known as the National Drug Code ("NDC"). FDA has assigned approximately 170,000 NDCs to drug products. The drugs and corresponding NDCs at issue in this case are listed below:

DRUG	NDC#
Sodium Chloride Injection	00074196607
Water for Injection 30 ml	00074397703
Vancomycin HCl 500 mg	00074433201
Water for Injection 10 ml	00074488710
Water for Injection 20 ml	00074488720
Sterile Water for Injection	00074488750
Sodium Chloride Injection	00074488810
Sodium Chloride Injection	00074488820
Sodium Chloride Irrigation	00074613802
Sodium Chloride Irrigation	00074613803
Sodium Chloride Irrigation	00074613822
Sterile Water for Irrigation	00074613902
Sterile Water for Irrigation	00074613903

Sterile Water for Irrigation	00074613922
Vancomycin HCl 5 gm	00074650901
Vancomycin HCl 1 gm	00074653301
Vancomycin HCL 500 mg Add-Vantage	00074653401
Vancomycin HCl 1 gm Add-Vantage	00074653501
5% Dextrose in Water 50 ml	00074710013
5% Dextrose in Water 100 ml	00074710023
Sodium Chloride Injection	00074710102
Sodium Chloride 0.9% 50ml	00074710113
Sodium Chloride 0.9% 100 ml	00074710123
Dextrose Injection	00074712007
Sodium Chloride Irrigation	00074713809
Sterile Water for Irrigation	00074713909
Dextrose 5%/ Kcl/NaCl 1000 ml	00074790209
Dextrose Injection	00074792202
5% Dextrose in Water 500 ml	00074792203
5% Dextrose in Water1000 ml	00074792209
Dextrose Injection	00074792336
Dextrose Injection	00074792337
Dextrose 5% and 0.225% NaCL Injection	00074792409
Dextrose 5% and 0.225% NaCL Injection	00074792609
5% Dextrose/ NaCl 0.9% 1000 ml	00074794109
Sodium Chloride Irrigation	00074797205
Sterile Water for Irrigation	00074797305
Sodium Chloride 0.9% 250 ml	00074798302
Sodium Chloride 0.9% 500 ml	00074798303
Sodium Chloride 0.9% 1000 ml	00074798309
Sodium Chloride Injection	00074798436
Sodium Chloride Injection	00074798437
Sodium Chloride Injection	00074798509
Water for Injection1000 ml	00074799009
Acyclovir Sodium 500 mg	00074442701
Acyclovir Sodium 1 gm	00074445201

31. Drug manufacturers, such as Abbott, have not typically submitted claims for reimbursement to federal health care programs. Instead, Abbott marketed its products to its Customers, who then purchased the products either directly or through wholesalers based on a price the Customers negotiated with Abbott. In addition to using wholesalers, Customers also

purchased Abbott products through group purchasing organizations ("GPO"), who negotiated prices on behalf of Abbott's Customers. However, as described in ¶¶ 111-138 below, Abbott also had a business unit that, among other activities, operated home infusion pharmacies and actually submitted reimbursement claims for drugs on behalf of various clients.

32. Abbott's Customers then submitted claims for payment for Abbott products to Medicare and Medicaid after dispensing or administering Abbott drugs. Medicare and Medicaid reimbursed some of the claims submitted by Abbott's home infusion pharmacies. In other instances, Abbott administered reimbursement claims for certain home infusion clients and collected portions of those clients' Medicare and Medicaid reimbursements as compensation for those services.

33. For the most part, in the Medicaid program, claims submitted by retail pharmacies are processed and tracked using the NDC of the drug.

34. The Medicare program generally uses the Healthcare Common Procedural Coding System ("HCPCS") to reimburse for drugs. The HCPCS utilize 5-digit alphanumeric codes to identify and bill for medical products and supplies. The codes at issue here are listed below:

HCPCS	**Description**
J2912	Sodium Chloride, .9 percent, per 2 ml
J3370	Vancomycin HCl, 500 mg
J7030	Normal Saline Solution, 1000 cc
J7040	Normal Saline Solution, 500 ml
J7042	5 percent Dextrose/Normal Saline Solution, 500 ml
J7050	Normal Saline Solution, 250 cc
J7051	Sterile Saline or Water, up to 250 cc
J7060	5 percent Dextrose/Water, 500 ml
J7070	D-5-W, 1000 cc
J7110	Dextran 75, 1000 ml
J7130	Hypertonic Saline Solution, 50 or 100 mEq, 20 cc vial

35. During the relevant period, Abbott usually reported prices to various price publishers and services on an annual basis. The price publishers used the information to publish pricing compendia.

36. The reimbursement amounts for claims submitted by Abbott or Abbott's Customers for the drugs at issue in this Complaint were directly influenced by Abbott's false price representations. The information contained in the published pricing compendia was used by most third party payor insurance companies, including the Medicare and Medicaid programs, in determining the reimbursement rates for prescription drugs. Abbott documents show that Abbott knew of the impact of its price representations on government reimbursement on claims submitted by its Customers for its drugs. Abbott documents also show that the company actively marketed the government-funded profits or "spreads" on its drugs created by its false price representations.

37. No governmental payor knew of or sanctioned Abbott's conduct as set forth in this Complaint, i.e., its deliberate manipulation of its published prices for certain of its products to induce its Customers to purchase those products.

D. Medicaid Reimbursement Formulas

38. When reimbursing for drugs, the State Medicaid programs' goal has been to pay an amount which, in the aggregate, reflects the lower of (1) the estimated acquisition cost ("EAC") of covered drugs, plus a reasonable dispensing fee, or (2) a provider's usual and customary charges to the general public. To determine the EAC for a covered drug, State

Medicaid programs are required to develop reimbursement formulas that must be approved by the Secretary of HHS. 42 C.F.R. §§ 447.331, 447.332, and 447.333 (2005).

39. While the specific reimbursement formulas vary from state to state, the various State Medicaid programs have generally reimbursed for each drug based on the lowest of (a) the EAC as set by the states, (b) the maximum allowable cost ("MAC") set by the state Pharmaceutical Reimbursement Boards, or (c) the providers' usual and customary charge. For multiple source drugs subject to a federal upper limit, states must in the aggregate not pay more than those limits. 42 C.F.R. §§ 447.331, 447.332 and 447.333 (2005).

40. The states' methodology for arriving at EAC includes:

A. discounting a percentage off of the Average Wholesale Price ("AWP");

B. adding a percentage to the Wholesale Acquisition Cost ("WAC") ; and/or,

C. requiring the drug companies to certify prices directly in writing to the Medicaid program in response to state requests for particular pricing information.

41. AWP is used to refer to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail Customer who then administers it to a patient. WAC is used to refer to the price at which a pharmaceutical firm typically sells a drug to wholesalers who would then resell it to a retail Customer.

42. While the majority of states use published AWPs to calculate reimbursement, approximately six states (Alabama, Florida, Maryland, Massachusetts, Rhode Island and Texas) have used the wholesale acquisition cost ("WAC") to set the EAC.

43. The AWPs and WACs relied upon by the State Medicaid programs have generally been those published by (1) Thomson Publishing, publisher of the *Red Book* and various other price publications, (2) First Databank, publisher of the *Blue Book* and other electronic price publications; or (3) Medi-Span, Inc., publisher of an electronic or automated price service and the Hospital Formulary Pricing Guide. Thompson Publishing, First Databank and Medi-Span, Inc. are hereafter referred to as the "Publishers" and their various publications and data services are hereinafter referred to as "Price Publications."

44. In addition to relying on the manufacturers' reported prices as published in the Price Publications, some State Medicaid programs also received price representations directly from manufacturers, and relied on these representations to confirm the accuracy of the figures they use to determine state reimbursement amounts. For example, the State of Texas required drug companies to submit their prices directly to the Texas Medicaid program in a signed certification attesting to the accuracy of the price information.

E. Medicare Reimbursement Formulas

45. From 1992 through 1997, Medicare based its reimbursement for multi-source generic drugs, the drugs at issue here, at the lower of the EAC or the median AWP of all generic forms of a drug. 42 C.F.R. § 405.517 (1992-1998). In general, Medicare relied on median AWPs to set reimbursement rates.

46. From January 1, 1998, until December 31, 1998, Medicare based its reimbursement for all generic forms of a drug at 95% of the median AWP for the drug. Balanced Budget Act of 1997, 42 U.S.C. § 1395u(o); 42 C.F.R. § 405.517 (1998).

47. From 1999 through 2004, Medicare based its reimbursement for all generic forms of a drug at the lower of (1) 95% of the median published AWP for the drug; or (2) the AWP of the least expensive brand-name drug. 42 U.S.C. § 1395u(o); 42 C.F.R. § 405.517 (1999-2004).

48. After the reimbursement amount is calculated, Medicare pays 80 percent and the Medicare beneficiary is responsible for the remaining 20 percent co-payment. If the Medicare beneficiary is also a Medicaid recipient, the Medicaid program generally pays the 20 percent Medicare co-payment.

49. Medicare generally relied upon the AWPs published by Thomson Publishing in its annual national compendium known as the *Drug Topics Red Book* ("*Red Book*"), as well as *Red Book* monthly updates to set reimbursement rates for covered drugs.

VII. ABBOTT'S SCHEME

50. From at least on or before January 1, 1991, and continuing through 2001, Abbott defrauded the United States by knowingly causing the Medicare and Medicaid programs to pay false or fraudulent claims for dextrose solutions, sodium chloride solutions, sterile water, Vancomycin and Acyclovir Sodium.

51. The specific dextrose solutions, sodium chloride solutions, sterile water, Vancomycin and Acyclovir Sodium products at issue herein are identified by NDC or HCPCS Code in ¶¶ 30 and 34 above and are hereinafter referred to jointly as the "Drugs."

52. Dextrose solutions, sodium chloride solutions, and sterile water are generic, water-based solutions used to facilitate the intravenous infusion of other drugs and for fluid replacement, and are commonly referred to as large volume parenterals ("LVPs").

53. Vancomycin is a powerful, intravenous antibiotic that Abbott has sold as a generic drug since 1988.

54. Acyclovir Sodium ("Acyclovir") is an antiviral drug used to treat several opportunistic viral infections, some of which are associated with HIV/AIDS.

55. Abbott marketed and sold its products, including the Drugs, to Customers.

56. The Customers purchased the products either directly from Abbott, through a GPO contract or through wholesalers.

57. The amount paid by a Customer was typically based on a price negotiated with Abbott or the GPO.

58. Regardless of the method of purchase, Abbott's Customers submitted claims for payment to Medicare and Medicaid when an Abbott product was administered to a program beneficiary. The claims submitted by Abbott's Customers were paid at amounts directly influenced by Abbott's false and fraudulent prices.

59. Abbott routinely disseminated false pricing information for the Drugs to the Pricing Publications. Abbott employees typically reported the false and fraudulent prices to the Price Publications annually, although they sometimes did so more often. On most occasions, Abbott reported inflated "List Prices" or "Direct Prices" (both referred to hereinafter as LP), WACs and/or AWPs. A LP is supposed to reflect the price paid by a Customer that buys drugs directly from Abbott and not through a wholesaler.

60. When Abbott reported a LP, some Price Publications (*e.g.*, *Blue Book*, which provided pricing information for the vast majority of the state Medicaid programs) calculated

Abbott's AWPs by applying a markup – usually 18.75% – to the LPs. Abbott was aware of how the Price Publications set its AWPs and knew (1) that the markup remained constant and (2) that its LPs ultimately controlled the AWP reported by the Price Publications for many of its products. Abbott reported WACs for several of its drugs as well, but during the time period covered by the Complaint, the Price Publications used Abbott's LPs (plus the standard markup) to set the AWPs used by the Medicaid and Medicare programs.

61. In some circumstances, Abbott itself calculated and supplied the AWP which it sought to have published.

62. For example, in a January 16, 1996 letter from Abbott's Reimbursement Manager to Medi-Span, Abbott directly reported AWPs for two of its products.

63. Abbott documents also confirm its knowledge that the LPs it reported directly impacted the AWP. In a March 20, 1995 e-mail between Abbott employees regarding the reporting of new Vancomycin LPs, one employee notes, "Please notify Red Book and Medi-Span of these changes ASAP. They are the sources for creating the AWP that is important to [Abbott's] Alternate Site [sales division]."

64. Abbott also submitted false and fraudulent prices directly to state Medicaid programs. In an October 1, 1997, Abbott "Medicaid Coordinator" Tena Brown represented in a letter to the State of Texas Medicaid Program that the price on Abbott's Vancomycin 1 GM Fliptop vial- sterile, NDC 00074-6533-01 ("Vancomycin 1 GM FTV") was $583.70 for a package of 10, or $58.37 a unit. That led the Texas Medicaid program to set reimbursement for

Vancomycin 1 GM FTV at that price ($58.37 a unit). At the time, Abbott sold Vancomycin 1 GM FTV to certain Customers for $5.53 per unit, through a GPO called Oncology Solutions.

65. With extremely few exceptions, Abbott reported increasingly higher prices for the Drugs from at least on or before January 1, 1991 through 2001. At the same time, the prices Abbott actually charged to its Customers decreased or remained the same.

66. Abbott knew that the prices which it reported to the Price Publications directly affected reimbursement amounts paid by the Medicaid and Medicare programs. As Abbott's Manager for Reimbursement noted in an April 26, 1995 memorandum, "[h]aving a published [LP] that is high allows a provider to bill at that list price." The false or fraudulent prices Abbott reported to the Price Publications inflated government reimbursement amounts on claims submitted by Abbott's Customers for the Drugs. A chart setting out some examples showing the difference between the prices at which Abbott actually sold its drugs and the false prices reported by Abbott is attached hereto as **Exhibit 1**.

67. Abbott manipulated its LPs, AWPs and WACs to induce its Customers to purchase Abbott's products, including the Drugs, by marketing the huge profits that would result to its Customers.

68. Abbott was well aware of how the Government used its pricing information to reimburse Abbott products. For example, Abbott organized an internal entity known as the "Medicare Working Group." The group (1) was organized by high level Abbott executives, (2) involved representatives responsible for reimbursement issues from all major Abbott divisions, and (3) discussed and organized efforts to influence government reimbursement for drugs.

69. Documents from the Medicare Working Group establish that Abbott knew that AWP is based upon Abbott's reported price plus, according to the Medicare Working Group documents, "a mark-up of 15-20%." Minutes from a January 21, 1997 meeting note that this AWP based on Abbott's reported prices is subsequently reported in "the Red Book, Blue Book and Medispan Book and is used by Medicare, Medicaid and Commercial insurance carriers to determine reimbursement levels."

70. Neither the Medicaid nor the Medicare programs knew of or sanctioned Abbott's conduct as set forth in this Complaint, *i.e.*, the deliberate manipulation of its published prices to induce its Customers to purchase the Drugs. Abbott never disclosed the price reporting practices for the Drugs identified in this Complaint to the Medicaid or Medicare programs.

A. Vancomycin

71. Abbott first introduced its generic Vancomycin in 1988. Abbott's scheme to defraud the United States by causing inflated Vancomycin reimbursements ran from approximately 1989 through 2001. Over that time period, Medicare and Medicaid paid in excess of $75 million for Abbott's Vancomycin.

72. During that time period, Abbott reported increasingly higher LPs and AWPs for Vancomycin to the Price Publications while the actual contract prices at which Abbott sold Vancomycin to its Customers decreased significantly.

73. Abbott sold its Vancomycin in several doses and forms. The Vancomycin 1 GM FTV was the most common dose of Vancomycin reimbursed by Medicare and Medicaid.

Abbott's false and fraudulent price reporting on its Vancomycin 1 GM FTV represents how Abbott reported false and fraudulent prices on its other Vancomycin products.

74. When Abbott first introduced its Vancomycin 1 GM FTV in 1988, the published per unit AWP was $25.20. By early 2001, Abbott reported false prices that drove the AWP for Vancomycin 1 GM FTV to $76.42. At the same time, the price at which Abbott's Vancomycin was widely available to purchasers decreased to under $4.00 by early 2001; the difference (and potential profit) between the reported price and the actual selling price for Vancomycin 1 GM FTV was as great as $72.42 a dose, or more than 18 times the actual price at which Abbott sold Vancomycin 1GM FTV.

75. Abbott fully controlled and manipulated the AWPs for Vancomycin 1 GM FTV to boost its Vancomycin sales at the expense of third party payors, including Medicare and Medicaid.

76. Abbott's manipulation of its reported Vancomycin prices between 1989 and 2001 created spreads sufficient to induce increased sales of that drug. Internal memoranda from senior Abbott sales staff reveal that Abbott actively knew about and marketed the large spreads on several of its drugs, including Vancomycin. Those efforts proved successful; the percentage of Abbott's Vancomycin sales reimbursed by Medicaid increased from less than 10% in 1991 to approximately 70% in 2000.

77. Abbott's reporting of Vancomycin prices in 1995 exemplifies the manner in which Abbott manipulated the price of Vancomycin to maintain and grow its market share. In March 1995, Abbott temporarily reported dramatically lower LPs and AWPs for Vancomycin.

Prior to the March 1995 LP/AWP price change, the Price Publications listed a per unit LP of $50.90 for Abbott's Vancomycin 1 GM FTV, and a per unit AWP of $60.44 for that drug.

78. In late March 1995, Abbott reported a new LP of $15.00 for a unit of Vancomycin 1 GM FTV. Based on this new information from Abbott, the Price Publications published revised per unit prices for Vancomycin 1 GM FTV. They reported a LP of $15.00 and an AWP of $17.81.

79. Abbott received numerous complaints from Customers over the resulting decrease in the spread. Abbott deliberated internally on whether and by how much Abbott should again increase its spread so that it could reestablish the inducement that had come to be expected by its Customers. Abbott documents show Abbott's pricing personnel carefully considering the additional profits they could generate for Abbott's Customers if they artificially re-inflated the reported prices for Vancomycin 1 GM FTV at various levels.

80. Abbott subsequently reversed its earlier decision to lower its reported prices and instead raised its reported Vancomycin prices. In early May 1995, Abbott reported a new per unit LP for its Vancomycin 1 GM FTV of $32.95. The revised AWP for Abbott's Vancomycin 1 GM FTV became $39.13 (once the Price Publication applied the standard markup).

81. That reported price increase proved insufficient. Later that same month (May 1995), Abbott reported yet another set of prices for Vancomycin. The LP Abbott reported for its Vancomycin 1 GM FTV rose to $52.94 and its AWP rose to $62.86 (once the Price Publication applied the standard markup).

82. Thereafter, Abbott reported higher Vancomycin LPs and AWPs to the Publishers each year, despite decreases in its actual prices to Customers for Vancomycin over that same period. The AWP for Abbott's Vancomycin 1 GM FTV peaked at $76.42 per unit in early 2001 at the same time that the actual sales price was less than $4 per unit.

83. The false prices reported by Abbott directly impacted the amount Medicaid and Medicare reimbursed for Vancomycin. For example, in 1999 Abbott's Vancomycin 1 GM FTV was widely available for approximately $4.75 a unit. Yet, Abbott reported a per-unit Vancomycin LP in 1999 – which served as the baseline for determining the AWP – to First DataBank of $64.35. As a result, the 1999 AWP for Vancomycin 1 GM FTV was set at $76.42.

84. New York State's Medicaid program relied on the First DataBank prices to set its reimbursement rate for the Vancomycin 1 GM FTV. New York State's Medicaid reimbursement rate for the Vancomycin 1 GM FTV in 1999 was $68.77; the AWP for Vancomycin 1 GM FTV was $76.42 at the time. New York's reimbursement for Vancomycin 1 GM FTV was AWP minus 10%, a reimbursement formula generally similar to those of other states. Abbott's false price representations created a profit spread of approximately $64.02 for Abbott's Customers, on a drug that Abbott sold to those same Customers for approximately $4.75 a unit. The spread between the New York state Medicaid reimbursement for Vancomycin 1 GM FTV – directly influenced by Abbott's false price reporting – and the actual acquisition cost was 1,348%. The profit to Abbott's Customers was 13.5 times the typical acquisition cost for the drug.

85. Abbott's practice of price manipulation continued into early 2001. At that time, Abbott reported new, lower WACs to the Price Publications for many of its drugs, including

Vancomycin, without also reporting new LPs or AWPs. At the time Abbott submitted the new prices in early 2001, it had been under investigation by the Government for pricing fraud. In addition, members of the House Ways and Means Committee accused Abbott of engaging in price reporting misconduct that threatened public safety in the fall of 2000; the Centers for Disease Control had expressed concerns that over-prescription of Vancomycin could lead to the growth in the population of Vancomycin-resistant bacteria. Also, in October 2001, an Abbott joint venture, TAP Pharmaceuticals, Inc. paid $875 million to the Government to resolve its criminal responsibility and civil liability for fraudulent pricing and kickbacks in connection with the marketing of a drug called Lupron. When Abbott submitted reduced WACs, First DataBank changed the way it calculated Abbott's AWP. First Databank personnel set new AWPs for Abbott products by applying a 25% markup to the newly supplied WACs instead of setting Abbott's AWPs by applying a 18.75% markup to Abbott's still inflated LPs. Abbott tried to convince First DataBank personnel not to set Abbott's AWP by reference to these new, lower WACs; Abbott wanted First DataBank to continue to use Abbott's then still inflated LPs to maintain its inflated AWPs. First DataBank refused Abbott's request. Ultimately, Abbott reduced its LPs and WACs to reflect the average sales price for the Drugs on April 30, 2001.

86. The switch to using the lowered WACs drastically dropped Abbott's reported AWPs in 2001. For Abbott's Vancomycin 1 GM FTV, the AWP dropped from $76.42 per unit in early 2001 (when AWP was determined using the inflated LPs) to $17.72 per unit in 2001 (when AWP was set using the revised, lowered WACs). By 2002, the AWP for this product was down to $6.06 a unit.

87. As a result of the drop in AWP, the spread on the reimbursement by Medicare and Medicaid was reduced from $60-$70 a unit to approximately $2.00 a unit.

88. Abbott's Customers recognized that Abbott was responsible for creating and maintaining the spread. Numerous Customers complained to Abbott or the group purchasing organizations (GPOs) who negotiated prices on behalf of Abbott's Customers. A large Customer of Abbott went so far as to demand restitution for the almost $10.5 million in lost profits due to the decrease in spread resulting from Abbott's 2001 submission of lowered prices to the reporting agencies.

89. Internal memoranda from senior Abbott sales staff reveal that Abbott actively knew about and marketed the large spreads on several of its drugs, including Vancomycin, as an inducement to purchase Abbott's drugs.

90. Abbott's share of the Medicaid market has dropped steadily since the more accurate prices started being published in 2001 and thereafter went from approximately 70% in early 2001 to approximately 20% in 2004.

B. Large Volume Parenterals

91. In addition to false price reporting for Vancomycin, Abbott engaged in similar conduct with respect to its LVPs.

92. LVPs are essentially sterile water, usually mixed with either salt (sodium chloride) or sugar (dextrose). LVPs are cheap to produce and are sold at very low prices.

93. One of the most commonly utilized Abbott LVPs was 5% Dextrose in Water, 500 ml, NDC # 00074-7922-03 ("5% Dextrose 500 ml").

94. In 1993, Abbott's 5% Dextrose 500 ml could be widely purchased for as little as $1.80 for a 500ml bag.

95. The Red Book AWP for 5% Dextrose 500 ml in 1993 was $8.72.

96. Two years later, in 1995, the price for Abbott's 5% Dextrose 500ml was widely available for even less; one wholesaler was selling it at $1.50 for a 500 ml bag.

97. During the same two year period from 1993 to 1995 that the actual prices dropped, Abbott twice reported higher prices to the Price Publications for 5% Dextrose 500 ml. The AWP – based on Abbott's representations – increased by 5% in 1994 to $9.16 and was increased by an additional 3% in 1995 to $9.43.

98. Thus, while Abbott's price to the wholesaler dropped by 20% between 1993 and 1995 (from $1.80 to $1.50), Abbott caused its AWP to increase by 8%. By 1995, the spread between the AWP and the resale price of that wholesaler was 628%.

99. Abbott sold these products directly to Customers at prices comparable to those offered by the wholesaler.

100. Abbott continued to report increasing prices for 5% Dextrose 500 ml after 1995. By reporting increasingly inflated LPs, Abbott caused the Red Book AWP for 5% Dextrose in Water, 500 ml, NDC # 00074-7922-03 to increase in 1996 to $9.71, in 1997 to $10.20, in 1998 to $10.71, in 1999 to $11.25 and in 2000 to $11.80. Medicaid and Medicare used these reported prices to set their reimbursement levels. At the same time, Abbott regularly sold the product to its Customers for $1.50 or less per bag of the water-based solution.

101. Abbott's reporting of increasingly false and fraudulent prices for its 5% Dextrose 500ml reflects the manner in which Abbott implemented its scheme for all of the LVPs during the relevant time period. Abbott engaged in identical conduct with respect to the "prices" and marketing of the other LVP products and package sizes identified by NDC and HCPCS code in ¶¶ 30, 34 of this Complaint.

102. Abbott used the false and fraudulent prices Abbott reported to the Price Publications for these water solutions to manipulate reimbursement; the reported prices did not reflect the actual prices Abbott was charging to its Customers.

103. Due to Abbott's conduct, Abbott's Customers submitted inflated claims to Medicare and Medicaid and received millions of dollars in inflated reimbursement for these water and water-based solutions. Abbott profited off the scheme by increasing its sales volume and profits. Medicare and Medicaid have paid Abbott's Customers in excess of $100 million for Abbott's LVPs when the typical acquisition costs for those Customers were a fraction of that amount.

C. Acyclovir Sodium

104. Acyclovir Sodium (Acyclovir) is an antiviral drug used to treat several infections. The brand version, called Zovirax, was originally manufactured by Glaxo Welcome, Inc. Abbott began selling its generic version of the drug on April 22, 1997.

105. At the time Abbott launched its versions of Acyclovir in 1997, it reported a LP of $80.00 for the 500MG Dose of its generic version of Acyclovir (NDC#00074-4427-01). The

1997 Blue Book AWP for Abbott's Acyclovir Sodium 500MG was $95.00 (reflecting the standard price publication mark up on Abbott products of 18.75%).

106. By 1999, Abbott had raised its reported LP for its Acyclovir Sodium 500MG to $88.20; the AWP for that dose of Abbott's Acyclovir Sodium had risen to $104.74.

107. Yet, competition among manufacturers of Acyclovir drove the contract prices for the drug down sharply. In 1997, Abbott's Acyclovir Sodium 500MG could be purchased for $30.00. By 2000, the typical purchase price for Abbott's Acyclovir Sodium 500MG had eroded to around $11.

108. Thus, the spread on Abbott's Acyclovir went from as much as 316% at product launch in 1997 to as much as 960% by 2000.

109. Abbott actively marketed the reimbursement spread on Acyclovir to Customers, including Ven-A-Care, the relator in this matter. Ven-A-Care operated a home infusion pharmacy that largely serviced HIV/AIDS patients. On or around May 30, 1997, an Abbott national account manager directly marketed the spread on its Acyclovir Sodium to Ven-A-Care. That national account manager sent documents reflecting the spread on Abbott's Acyclovir and had conversations with Ven-A-Care where he explicitly marketed the spreads on Abbott's Acyclovir products.

110. On April 30, 2001, Abbott reported new LPs and WACs for its Acyclovir products. As noted above, the price reporting compendia changed the method it used to calculate Abbott's AWP. First Databank began using Abbott's WAC and applying a 25% markup. The LP for Abbott's Acyclovir Sodium 500MG dropped from $88.20 to $4.00; the WAC dropped to

$3.81. The per unit AWP – based on a 25% markup from the $3.81 WAC – for Abbott's Acyclovir Sodium 500MG dropped from $104.74 to $4.76. The revised LP, WAC and AWP was in keeping with the actual contract price for Abbott's Acyclovir Sodium 500MG, which by mid-2001 was around $4.00 a unit.

D. Abbott's Home Infusion Pharmacies, Home Infusion Partnerships and Consignment Arrangements.

1. Home Infusion Pharmacies

111. From approximately 1982 until, upon information and belief, 2003, Abbott owned and operated its own Home Infusion Pharmacies ("Abbott HI Pharmacies") as part of its Hospital Products Division's ("HPD"), Alternate Site Home Infusion Department.

112. Abbott's HI Pharmacies were located at various times in Atlanta, Georgia, Chicago, Illinois, Los Angeles, California, and in New Jersey. At some point in that period, the Abbott HI Pharmacy in Atlanta Georgia closed.

113. Abbott billed Medicare and Medicaid for products and services dispensed by the Abbott HI Pharmacies using Abbott's EIN number and Abbott's own Medicare and Medicaid provider codes.

114. Abbott HI Pharmacies stocked and dispensed Abbott products, including, without limitation, products identified in this Amended Complaint in ¶ 30, as well as other products produced and sold by Abbott and other manufacturers. Upon information and belief, Abbott stocked its own products at or near the manufacturing costs for those products. Upon information and belief, Abbott was able to acquire other manufacturers' drugs at reduced, contracted prices.

115. The Abbott HI Pharmacies billed Medicare and Medicaid through the "Abbott Reimbursement Department" in Abbott's HPD Alternate Site Home Infusion Department.

116. Each of the Abbott HI Pharmacies would operate as follows:

A. The Abbott HI Pharmacies would receive patient prescriptions from physicians, hospitals, outpatient clinics or other care providers.

B. Abbott's Reimbursement Department would ascertain whether the referred patient was eligible for reimbursement for his or her prescription costs through Medicare, Medicaid or a third party insurer.

C. Upon receipt of the prescriptions, the Abbott HI Pharmacies would fill the prescription and would, upon information and belief, at times provide pharmacist services.

D. After the prescriptions were filled by an Abbott HI Pharmacy, the Abbott Reimbursement Department would bill either Medicare, Medicaid or a third-party insurer for the dispensed drug or product, depending upon patient eligibility.

E. For those patients covered under Medicare or Medicaid, a reimbursement clerk in the Abbott Reimbursement Department would complete a paper or, at a later point, an electronic, Medicare HCFA 1500 form seeking reimbursement from Medicare or a Medicaid reimbursement form.

117. The HCFA 1500 forms or Medicaid reimbursement forms submitted by the Abbott Reimbursement Department would reflect Abbott's EIN number and provider number as the entity to be reimbursed.

118. Depending upon the drug and the state program, Medicaid would typically pay to Abbott the AWP or WAC-based reimbursement for drug or product for which Abbott's HI Pharmacy billed. Medicare would typically pay to Abbott the AWP-based reimbursement for drug or product for which Abbott's HI Pharmacy billed. Abbott would retain for itself as a profit the difference between the cost of the drug or product to Abbott and the amount of the AWP-based reimbursement ("Abbott HI Pharmacy spread").

119. Upon information and belief, Abbott did not disclose the Abbott HI Pharmacy spreads to the Medicare or Medicaid programs when it submitted reimbursement forms.

120. The amounts Abbott HI Pharmacies were reimbursed by Medicare and Medicaid regularly exceeded the cost to Abbott in stocking and dispensing the drugs and products dispensed by the Abbott HI Pharmacies – including its own.

121. In the case of the Abbott Drugs identified in this Complaint, Abbott's HI Pharmacies were reimbursed inflated amounts for any claims they submitted for those Drugs due to Abbott's fraudulent price reporting scheme.

2. Abbott's Home Infusion Partnerships and Consignment Arrangements

122. From approximately 1984 until, upon information and belief, 2003, Abbott HPD's Alternate Site Home Infusion Department entered into home infusion partnerships ("HI Partnerships") with various hospitals, care facilities and other medical entities. These HI Partnerships permitted Abbott's home infusion partners ("HI Partners") or – in some instances Abbott – to bill government health programs on behalf of its HI Partners for the Drugs identified in ¶ 30 at inflated reimbursement levels.

123. Abbott had at least 20 to 25 home infusion partners ("HI Partners") in these partnerships including, but not limited to:[3] University of Michigan's HomeMed, Children's Memorial Hospital of Chicago, Care Partners, Baylor, Harris Methodist, UniHealth, Intermountain, Cedars Sinai, University of Virginia, Seattle Children's Hospital, Cleveland Clinic, and University Hospitals of Cleveland.

124. Abbott entered into standard partnership agreements with the HI Partners and others. Under the terms of the partnership agreements, Abbott would:

A. Provide its HI Partners Abbott drugs and products free of charge on a consignment basis, including but not limited to, the Drugs identified in ¶ 30 of this Complaint;

B. Provide its HI Partners agreed upon services, including, on occasion, "reimbursement services;" and

C. Add the HI Partner to a group purchasing organization of which Abbott was a member, so that the HI Partner, or Abbott on behalf of the HI Partner, could purchase drugs and products that Abbott did not manufacture or sell ("Other Non-Abbott products") at a substantially reduced contract rate.

125. The HI Partner would dispense the drugs or products from its pharmacy. If the drug or product was an Abbott product, that product would be a consigned product that the HI

[3] These HI partners are described herein as identified by an Abbott witness. For some of these HI partners, the witness did not provide full and complete name information.

Partner would not pay for on an individual basis, or at any time prior to when the HI Partner billed Medicare or Medicaid.

126. As part of its "reimbursement" services for some HI Partners, Abbott's Reimbursement Department would submit claims to Medicare, Medicaid and other third party payors for drugs, medical devices and medical services on the HI Partner's behalf, using the HI Partner's EIN number and Medicare and Medicaid provider codes.

127. For patients covered under Medicare or Medicaid, an Abbott reimbursement clerk in the Reimbursement Department would complete a paper or, at a later point, electronic, Medicare HCFA 1500 form seeking reimbursement from Medicare, or the appropriate Medicaid reimbursement form seeking reimbursement from a State Medicaid program on behalf of the HI Partner.

128. Abbott provided reimbursement services to, among others, Care Partners, University of Michigan, Children's Hospital and the University of Virginia.

129. If Abbott was providing reimbursement services to an HI Partner, Abbott's Reimbursement Department would collect reimbursements from Medicare, Medicaid and other third party payors for claims submitted on behalf of that HI Partner. Those reimbursement amounts were collected in lock box bank accounts that, upon information and belief, were maintained in the name of the HI Partner or Abbott.

130. Upon information and belief, Abbott would never bill the HI Partners for the drugs and products it consigned to them, and would never expect payment for them. Abbott's payment for the consigned Abbott drugs would be some percentage of the HI Partner's entire pool

of collections from Medicare, Medicaid and third party payors, regardless of whether it was Abbott or the HI Partner that submitted the claim.

131. Under the Consignment Partnership Agreements, the HI Partners would never pay Abbott individual amounts for the drugs or products consigned to the HI Partner. The Medicare and Medicaid drug reimbursements were used by Abbott to compensate it for billing and consulting services not related to the provision of patient care.

132. For example, a December 1996 Consignment Partnership Agreement, required a HI Partner to pay Abbott 45.1 % of its gross revenue collections for all of its IVIG treatment, including any administration fee and/or any drug ingredient cost. Thus, Abbott would receive a percentage of any inflated reimbursement spreads for the Drugs identified in ¶ 30 of this Complaint that were provided to its HI Partners on consignment.

133. Abbott never disclosed to the Medicare or Medicaid programs that it was directly profiting from the reimbursement spreads in the above-described arrangement with the HI Partners.

134. If an HI Partner would not contract for reimbursement services, the HI Partner would submit the claims to Medicare and Medicaid and directly collect the reimbursements. However, Abbott would still consign its drugs and products to the HI Partner and still share in a percentage of the total collections collected by the HI Partner.

135. Several state Medicaid programs would reimburse for Abbott drugs covered by this arrangement at amounts tied to the AWPs or WACs for those drugs. Medicare also reimbursed for Abbott drugs covered by these arrangements at amounts tied to the AWPs for the

Abbott drugs. That amount would then be paid to the HI Partner, who in turn would provide a percentage share to Abbott of its entire collections as payment for various types of categories of services.

136. The cost to Abbott in stocking the HI Partner's warehouses with Abbott and non-Abbott drugs and products was far less than the amounts reimbursed by Medicare and Medicaid for those drugs and products.

137. Abbott did not disclose to the Medicare and Medicaid programs that the drugs and products it sought reimbursement for from Medicare or Medicaid actually cost Abbott far less to consign to the HI Partner than the ultimate Medicare or Medicaid reimbursement amount.

138. In the case of the Abbott Drugs identified in this Complaint, Abbott's percentage of HI Partner reimbursements Abbott that collected was improperly inflated due to Abbott's fraudulent price reporting scheme.

FIRST CAUSE OF ACTION

(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1))

139. Plaintiff repeats and realleges ¶¶ 1 through 138 as if fully set forth herein.

140. Abbott knowingly caused or caused to be presented false or fraudulent claims for payment or approval to the United States for the Drugs for reimbursement that were substantially higher than providers' actual acquisition costs for the Drugs and based on reported prices that were fraudulently and artificially manipulated by Abbott. Abbott knowingly used the spread as an unlawful inducement in violation of the federal anti-kickback statute, causing resulting false and fraudulent claims to be submitted.

141. By virtue of the false or fraudulent claims that Abbott caused to be made, the United States has suffered damages and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,000 and up to $10,000 for each violation occurring before September 29, 1999, and not less than $5,500 and up to $11,000 for each violation occurring on or after September 29, 1999.

SECOND CAUSE OF ACTION

(False Claims Act: Making or Using False Records or Statements to Cause Claims to be Paid)
(31 U.S.C. § 3729(a)(2))

142. Plaintiff repeats and realleges ¶¶ 1 through 138 as if fully set forth herein.

143. Abbott knowingly made, used, or caused to be made or used, false records or statements – *i.e.*, the false certifications and representations made or caused to be made by defendants to state Medicaid programs when seeking to ensure that the Medicaid programs would reimburse for the Drugs, and the false representations to the Publishers upon which Medicare and Medicaid relied – to cause false or fraudulent claims paid or approved by the United States.

144. By virtue of the false records or false statements made by Abbott, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,000 and up to $10,000 for each violation occurring before September 29, 1999, and not less than $5,500 and up to $11,000 for each violation occurring on or after September 29, 1999.

THIRD CAUSE OF ACTION

(Unjust Enrichment)

145. Plaintiff repeats and realleges ¶¶ 1 through 138 as if fully set forth herein.

146. This is a claim for the recovery of monies by which Abbott has been unjustly enriched, including (1) profits earned by Abbott through its HI Pharmacies and Consignment Partnership Agreements and (2) profits from increased sales resulting from the illegal inducements that Abbott arranged to be paid to its Customers.

147. By obtaining monies as a result of its violations of federal and state law, Abbott was unjustly enriched, and is liable to account for and pay such amounts, which are to be determined at trial, to the United States.

148. By this claim, the United States requests a full accounting of all revenues (and interest thereon) and costs incurred by Abbott on sales to Customers to whom it arranged for unlawful inducements, and disgorgement of all profits earned and/or imposition of a constructive trust in favor of the United States on those profits.

FOURTH CAUSE OF ACTION

(Common Law Fraud)

149. Plaintiff repeats and realleges ¶¶ 1 through 138 as if fully set forth herein.

150. Abbott made material and false representations concerning the prices of the Drugs with knowledge of their falsity or reckless disregard for the truth, with the intention that the United States act upon the misrepresentations to its detriment. The United States acted in justifiable reliance upon Abbott's misrepresentations by making payments on the false claims.

151. Had the true facts of Abbott's false price reporting as set forth in this Complaint been known to the United States, the United States would not have paid for Abbott products.

152. By reason of these payments, the United States has been damaged in an as yet undetermined amount.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Abbott, jointly and severally, as follows:

1. On the First and Second Causes of Action, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.

2. On the Third Cause of Action, for the damages sustained and/or amounts by which Abbott was unjustly enriched, including an accounting of all revenues unlawfully obtained by Abbott, the imposition of a constructive trust upon such revenues, and the disgorgement of the illegal profits obtained by Abbott, plus interest, costs, and expenses, and all such further relief as may be just and proper.

3. On the Fourth Cause of Action, for compensatory and punitive damages in an amount to be determined, together with costs and interest, and for all such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

For the United States of America,

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Dated: June 4, 2007

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above **UNITED STATES' FIRST AMENDED COMPLAINT** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Mark A. Lavine
Dated: June 4, 2007 Mark A. Lavine

EXHIBIT C

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CITIZENS FOR CONSUME, et al. . CIVIL ACTION NO. 01-12257-PBS
Plaintiffs .
.
V. . BOSTON, MASSACHUSETTS
. JULY 20, 2007
ABBOTT LABORATORIES, et al .
Defendants .
. . . . . .

TRANSCRIPT OF MOTION HEARING
BEFORE THE HONORABLE MARIANNE B. BOWLER
UNITED STATES MAGISTRATE JUDGE

APPEARANCES:

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Proceedings recorded by digital sound recording, transcript produced by transcription service.

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I N D E X

P R O C E E D I N G S

(Court called into session)

THE CLERK: The Honorable Marianne B. Bowler presiding. Today is July 20, 2007. The case of Citizens For Consume et al. v. Abbott Laboratories et al., Civil Action No. 01-12257 will now be heard. Would counsel please identify themselves for the record.

MR. NEIL: John Neil on behalf of the United States.

MR. GOBENA: Gejaa Gobena on behalf of the United States.

MR. DRAYCOTT: Justin Draycott on behalf of the United States.

THE COURT: Thank you.

MR. DALY: Good morning, Your Honor, Jim Daly on behalf of Abbott Laboratories.

THE COURT: Thank you.

MR. ANDERSON: Good morning, Your Honor, Jared Anderson counsel for the Relator.

MR. WINTER: Good morning, Your Honor. I'm Raymond Winter, counsel for the state of Texas.

THE COURT: All right, thank you very much. Well we're start with these and take them in the order in which they were filed. So the first is Docket Entry No. 3959 which is Abbott's renewed motion to compel. Mr. Daly?

MR. DALY: Your Honor, is this the one on the

deliberative process privilege?

THE COURT: It is.

MR. DALY: We have two--

THE COURT: It is.

MR. DALY: --motions today on, motions to compel. Thank you, Your Honor.

THE COURT: You're welcome.

MR. DALY: The - as the Court is well aware, the government has sued Abbott for fraud. They've sued Abbott for violations under the False Claims Act. They've claimed that we mislead them and deceived them and made misrepresentations. They claim in their complaint that they reasonably relied on the things that Abbott told them in their price representations. They said they didn't know about the spreads. They said they would have acted differently had they known. And they say that Abbott withheld information that was critical to the government's consideration and deliberations about what kind of reimbursement methodology to use. That's the essence of the complaint against us.

Meanwhile there are a host of documents that the government, about 600 in total, that the government has withheld on the basis of what they call the deliberative process privilege. They have, for example, they've withheld all drafts of any document, whether it's a letter or a report or anything, claiming that drafts are inherently deliberative,

whatever that means. We've cited cases that say that being a draft doesn't mean anything under the deliberative process privilege. They have minutes of meetings between OIG which has done all of these reports that the Court has seen in other context where they, when they get ready to do a report all the OIG folks get together and talk about what they're going to do and why they're doing it. And then when they're done they ship a copy of it over to CMS, the plaintiff agency, and then they have a meeting and they talk about it. That's called the exit conference. And there are minutes and notes and memoranda written about those where people are sitting around talking about the spreads, talking about how AWP is much higher than AAC or actual acquisition costs or average sales price. And they talk about it back and forth and somebody writes up minutes. That's the consideration and the deliberation of the facts that they say in their complaint that they don't have and yet all of that stuff is being kept from us.

There are listings in both privilege logs of the OIG and CMS that talk about consideration of alternative proposals for recommendations. In fact there's one that says alternative Medicare Part B reimbursement mechanisms and the pros, cons and potential impact of each. That's this case. That's what were they - as Judge Saris has said over and over again she wants to know what they were doing, what they were thinking, what they agreed to, what they didn't agree to and what they understood

and what they didn't understand. Here's a document on the privilege log that says they're considering all these alternatives. Not only doing that, but examining and discussing the pros and cons and potential impact of each. And yet that goes to the heart of their claim. It goes to the heart of Abbott's defense and we don't have it. So we have all these and there's a tremendous amount of examples that we can use but there are 600. And so what it boils down to is they say we didn't know. They say they reasonably relied. They say that we misled the federal government and caused them damages, but we're not going to give you the documents that show what we knew and what we thought and what we considered. It's a fraud claim--

THE COURT: You'll get your chance.

MR. DALY: There's no reasonable reliance.

THE COURT: Just sit back and relax.

MR. NEIL: Sorry, Your Honor.

MR. DALY: These documents are documents that are written within OIG. People writing draft reports, people writing memoranda's talking about all the data that they're collecting, all the stuff that shows the disparity between actual acquisition cost and AWP, documents within CMS, documents between those agencies when they get together and talk about it. Documents - we've asked them for the legislative affairs documents. They just told us, no, you're

not getting them cause that's talking about laws and things we thought about when we were thinking about what kind of methodology we might follow and you can't have them. Deposition transcripts, we've cited them in the briefs, we've attached the transcripts, asking people, you know, in depositions, well you had a meeting, did you talk about alternatives? Direct you not to answer. Well, can you at least tell me whether alternatives were discussed? Direct you not to answer. That's the deliberative process privilege. They're taking this thing so broadly and so expansively that, you know, the everyday decisions about what word to write in a report is trying to be wrapped up in the deliberative process privilege cause every minute that goes by is some kind of a decision or another and they just stretch this thing beyond anything that the deliberative process privilege would mention and, or would countenance.

Now what I'd like to propose, Judge, is that we've cited the law in our brief. When the plaintiff comes in, and the plaintiff is the United States government, and the plaintiff comes in and sues for fraud, says it doesn't reasonably rely - that it reasonably relied on our representations, says it didn't know and says that it would have acted differently and says that we withheld information from them that would have caused them to take a different course. That the law, and we cite, you know, really a bunch of

cases, but we do have the *Garner Supply* case which we cited from this district and we do have the *Department of Economic Development v. Arthur Anderson*, which is a Southern District of New York case, two leading cases on the subject. They basically say when what the government knew and understood is at issue, where adjudication of fraud claims turns on issues of knowledge, reliance and causation, all of which apply to fraud and the False Claims Act, direct evidence of causation is irreplaceable, and they ordered that all this stuff be turned over.

So our position is that when the plaintiff brings the action and puts what it knew and puts what it relied on at issue in the case you can't then say, oh, well you know, we did all that but you can't see what we actually thinking. You can't see what we were actually doing and thinking about and talking about within our own agencies and between agencies and that's not fair. And, you know, we have a lot of other arguments that, which I'm happy to go through with the Court but – arguments about, you know, where's the prejudice here? I mean, we're talking about meetings that we had 15 years ago or 10 years ago or five years ago or indeed 20 years ago that no one's going to be chilled about. I mean the law has changed, the Medicare Modernization Act has been entered into, a variety of arguments like that. Procedural arguments where they did not come in, they haven't identified the prejudice.

They haven't identified what decision cause to be wrapped within the deliberative process privilege it has to be a pre-decisional document that relates to an identified decision that was ultimately made. They haven't done that for any document on their list. And they come in with affidavits only after we file our motion to compel in which we've cited several cases that that alone, the failure to come in on day one with an agency head or a senior person within the agency to claim and identify the privilege in the first instance without waiting for a motion to compel, that that alone is reason enough to wipe out the privilege.

So I can go through that. I can go through examples with the Court. We can look at the privilege logs itself if you want but my proposal would be we don't have to do any of that and the Court shouldn't have to do any of that if the privilege does not apply. And I think clearly under the case law it doesn't, so if the Court wants to hear from the government on that maybe it makes sense.

THE COURT: All right. Why shouldn't I grant your brother's motion?

MR. NEIL: Thank you, Your Honor. Your Honor, my brother is asking this Court to vitiate or to entirely eliminate an exceptionally important governmental privilege in order to obtain information that, one, they already have access to and, two,--

THE COURT: Well, explain yourself--

MR. NEIL: --from other sources.

THE COURT: Explain yourself on that.

MR. NEIL: Let me explain myself. I think the best way to do that is to look into a specific context. Let's take a look at the OIG privilege log. Abbott has requested the work paper files from a very, very large number of OIG audits and inspection reports. What have we produced in response to my brother's request for production in the OIG context? Well we produced the reports themselves. We've produced CMS's comments on those reports. We produced OIG's response to CMS's formal comments on those reports. We've produced all of the underlying facts and data--

THE COURT: We're not arguing about what you've produced.

MR. NEIL: Fair enough, Your Honor, but--

THE COURT: It's about what you haven't produced.

MR. NEIL: What we have not produced is a very, very narrow fraction of what we've produced in this case. Mr. Daly suggested that it's important to his client's to obtain information about what individuals in the government thought, knew, understood, about drug reimbursement. They have access to that. They've deposed the authors of any number of these OIG reports. They've asked them specifically what fact did you rely on? What did you know about the drug reimbursement

system? What did you know about my client's conduct? All kinds of specific questions. Those have not generated a request not to answer. They have access to all of this information.

THE COURT: Then why are you objecting - if those have not generated objections, why are you concerned about the underlying documents?

MR. NEIL: Because the underlying, well, certain underlying documents. There are certain categories of underlying documents that we've asserted a privilege over and the reasons are set forth in the attached declarations. Essentially, I mean for example in the OIG, you know, in the OIG declaration by Robert Vito who's a regional inspector general with the Office of Inspector General, he, Mr. Vito set forth the process by which inspection reports are finalized. There's a very vigorous internal process in which drafts are circulated, program staff make comments on those drafts, make suggestions, and then the draft is finalized after a meeting with CMS in which representatives from both sides hash out various issues and concerns. Then at the end of that process CMS comments, OIG finalizes the report and the entire product is published.

Mr. Daly and Abbott has access to the final report. They have access to CMS's final formal comments. And they have access to OIG's response to CMS's formal comments. They can

ask individuals within OIG what they thought, what they knew, what they understood and those kinds of questions won't generate objections on this basis. The drafts themselves and the comments on the drafts of these OIG reports are really the core of the deliberative process. It is the process of individuals within the Office Inspector General hashing out, debating, discussing, noting objections to a non-final document that then eventually is finalized. I think Mr. Vito articulated the harm that he felt would come to his program staff if those kinds of comments, if the program staff knew that those kinds of comments were going to be fought over in litigation 10 or 15 years down the road.

So the situation with CMS, not to focus exclusively on OIG. The situation with the CMS in the carrier logs is somewhere. Abbott filed a request for production - well, let me step back. In response to subpoenas the United States received in 2004 when the United States was a third party in this MDL, The United States produced documents to a large number of defendants including Abbott. We produced 115,000 pages of documents approximately in response to that subpoena. We withheld approximately 600 documents on deliberative process grounds. In the instant case Abbott filed a request for production asking for all of the documents that we withheld on deliberative process grounds in our response to the subpoena. We did a re-review and agreed to release about 200 such

documents but we retained the privilege of approximately 400 of those documents.

Abbott's got 115,000 pages of documents from that CMS production. They deposed three former CMS administrators, APEX witnesses, and they deposed them for a total of five days with a sixth day scheduled. They've asked these administrators about their conversations with Congress, conversations with congressional staff, conversations within the agency that aren't deliberative. They've obtained an enormous amount of information from these individuals about what they knew, what they understood, what they believed about drug reimbursements, about Abbott, about any number of topics.

So what we're trying to protect here is not an extraordinary amount of information. We're, you know, Abbott has access to information about what the government knew, understood and believed in, you know, a variety of ways. We're producing that information. We're continuing to produce that information. And Abbott can, you know, continue to ask witnesses about it. We're only withholding a very, very narrow band of documents and a very, very narrow set of information that goes to the core of the deliberative process. We've been judicious.

One other point before we turn back to my brother, there's a real question about the relevance to the specific allegations in this case of the documents on the logs. One

thing that Judge Saris has really made clear on a number of statements and rulings that when evaluating issues in this MDL, you really have to look at it on a company by company, drug by drug basis. I know that Your Honor has embraced that reasoning in a number of your own rulings. Precious few of the documents on any of these privilege logs involve Abbott at all. They don't mention Abbott drugs. They don't mention Abbott the company. Of the more than 600 documents on the three logs, a very, very rough calculation that I did, if you include Lupron which is not an Abbott drug but is a drug manufactured by TAP in which Abbott is a joint venture, I counted about 60, 60 documents that even mentioned Abbott in any way. That's something I would have to confirm by going to the documents themselves but about 60 documents--

THE COURT: Are you willing to give those 60 over?

MR. NEIL: I don't think they're relevant but I'd be willing to give them to you for an *in camera* review.

THE COURT: I'm glad you're willing.

MR. NEIL: It's better than 600, Your Honor. So that would be one sort of compromise step that I think we could take here that might facilitate this.

THE COURT: Okay. I'll think about it. You know, the two least favorite words for Judges are *in camera* and pro se.

MR. NEIL: We'll understand. Thank you.

THE COURT: Enjoy being a juror, Mr. Shapiro?

MR. SHAPIRO: Would you make me decide?

THE COURT: No.

MR. DALY: Your Honor, a couple of things.

THE COURT: Just briefly, Mr. Daly, and then we'll move on to the next motion.

MR. DALY: Certainly. If you look at the deposition testimony that we've cited in our briefs and attached, one of things that I think is important to mention is that we've deposed a lot of people. We're asking them about meetings and events and decisions that were made five, 10, 15 years ago because that's all within the period that the government is suing us for. Witness after witness is saying I don't remember. That's 10 years ago, I can't - how can you expect them to remember that? And we're like, well, we wish we hadn't taken so long but it's not our doing, so these documents are a critical source of information for us. And one thing that the Court did not hear in Mr. Neil's presentation is any basis for having the privilege apply.

They don't address the legal argument that when you put reliance, causation, lack of knowledge, you misled us, you withheld from us, at issue, which they've done by the allegations of their complaint, it's out the window. You didn't hear anything about that because there's nothing to say. And I think it's a policy position of the government that they

try to maintain these privileges wherever they can. But in this case as the cases we've cited have held, when you put it at issue when it is at issue, it's gone. And giving the 60 documents, I mean I definitely object to that. I don't think we need an *in camera* review of anything here because as a legal matter they have - the privilege doesn't apply because they've put those deliberations, they've put the reasons why they did what they did and didn't do what they didn't do at issue by suing us for fraud. And I do object to getting 60, Judge. And I do object to getting an *in camera* review, and I don't have the sense the Court wants to do it today certainly but, you know, I'd be prepared to walk through all 400 with them and I think you'd see, I even have some examples, but we're talking about things that are--

THE COURT: 400 or 600?

MR. NEIL: Your Honor, there are approximately 600 documents on the three logs.

THE COURT: Yeah.

MR. DALY: But--

THE COURT: All right. I've heard enough on that. So let's move on to docket entry No. 4135, which is Abbott's motion to compel United States and the Relator for adequate responses.

MR. DALY: Your Honor, this is our motion to compel, which I think through the happening of events and the passage

of time and some discussions and some additional productions has limited itself to three broad areas which I'll try to get through very quickly. The first one relates to our interrogatory 3 which simply asks for who received copies of the various OIG reports and other studies, GAO reports, things that were done, all of the documents that the Court has seen several times in various iterations depending on what motion is before you. But we've said, okay, who got those? And, you know, they've objected and said well we can't go tell you everybody who got it because we don't know. So we've said, okay, that makes sense. I'm not asking you to certify everybody who ever got one of these things but can you at least give us a distribution list? I mean was there a distribution list, you know, and it would change over time as to who would get this. Is there a person or persons that we can talk to who could tell us who circulated these things? Things of that nature of a very general nature and we've been foreclosed on that and we would like to have that.

THE COURT: All right. Why not, Mr. Draycott?

MR. DRAYCOTT: First of all, they can't have it to the extent we have it and the exhibits to the government's opposition to the motion to compel demonstrates how we've been trying to turn precisely this information over and have been trying to make it available. And it in fact has been turned over and has been used by Abbott at deposition and if the Court

will permit me I'll refer Your Honor to a couple of the exhibits.

First it's important to understand the process of the generation of these reports and where the critical interaction is.

THE COURT: Well, let's just cut right to it. Is there somebody who would know?

MR. DRAYCOTT: No. I think if Your Honor would permit me, I'll explain why this is - what the process is. There is an inspection is begun at within different offices at OIG. The report is generated and what is a critical, well there's what's called a final draft of that report. That draft is then sent over to in this case, CMS and CMS then comments on it. Now with respect to - and later a final draft comes out and attaches a memorandum which contains the agency comments. That draft is then posted on an OIG website and has been for years and that is just available and out there in the public domain. So this distribution--

THE COURT: Starting in what year was it posted on the website?

MR. DRAYCOTT: I don't - I was afraid Your Honor might ask that--

THE COURT: Then you should have known.

MR. DRAYCOTT: Well, it's as long as - I've been trying actually to find that out. It's been as long as I can

remember and as long as anybody can remember so as long as it's been available, but we'll certainly obtain that information. But there's no doubt those reports have been generated and posted and they've been in the public domain. But if Your Honor will permit me, with respect to--

THE COURT: Do you have any idea, Mr. Daly, about - are you familiar with this website or?

MR. DALY: Yes, Your Honor. I don't know the year that it started either, Judge, I apologize.

MR. DRAYCOTT: But that, at any rate that is how these reports are currently posted. So if I may back up to the final draft and direct your attention - the other thing that Mr. Neil explained is that with respect to that final draft it's then, there's then a referral about the final draft. And so that's the draft that then goes to the agency and which it gets the agency response. And so the final report is this thing from the final draft is the critical issue.

Now within the work papers if I can direct Your Honor's attention to our Exhibit 4. I don't know if you have it in front of Your Honor--

THE COURT: I don't.

MR. DRAYCOTT: But what it is is these are rosters. Now the material that hasn't been reviewed from these work paper productions are the types of information they're set out in Exhibit 4 which is a roster of the conference that occurred

between CMS and OIG regarding the report. This is, if you'll permit me to quote those, and this is where the rubber meets the road, this is who was consulted on the final draft. And if you look at the first page of Exhibit 4 it identifies not only the individuals but their affiliation within CMS. So this is the most direct, this is absolutely the core document if you want to look at where the information that is being generated in the context of inspection is going within CMS. It's the roster that reflects the exit conference with respect to that draft.

THE COURT: All right. Mr. Daly, what do you think is out there that you don't have?

MR. DALY: Your Honor, we've asked in depositions, for example, who's in charge of circulating the stuff. Counsel is talking about the pre-finalization of the report where you, you have these meetings where people are talking about what the reports say. That's one of the things we want that they're hiding under the deliberative process privilege. But what I'm asking for is where does the report go after it's done. In other words, before it was posted on the internet which can't be any later in time than probably the late `90's and a lot of these reports go back to 1992, 1991, even the late `80's. Who was in charge of circulating those? We want to know what federal agencies it went to. We want to know who was in charge of sending it to the states and by what means because a lot of

these are Medicaid--

THE COURT: All right. The government's ordered to produce somebody to address these issues.

MR. DALY: Thank you, Your Honor.

THE COURT: Next?

MR. DALY: Your Honor, the next category is what I'll call generally documents gathered during their 11 year investigation of Abbott before they unsealed. And basically what we're asking for here is to give us copies of subpoenas or certificates of their civil investigative demands that you served on third parties. Give us the documents that you got pursuant - I mean if we had been in litigation if they'd unsealed we'd have all this stuff because they'd be Rule 45 subpoenas. So they spent 11 years digging up stuff and dealing with their investigation. We'd like to have that. We're not asking for their work product. We're asking for stuff that they've got. They've told us for example--

THE COURT: Well let's narrow it into categories.

MR. DALY: Okay.

THE COURT: Other than stuff.

MR. DALY: Sorry, Judge. Witness statements, they've told us that we can have those. They say we've gotten them in the Texas litigation. We've asked, well, we--

THE COURT: Okay, any additional witness statements that have not been produced.

MR. DRAYCOTT: They've all been produced.

MR. DALY: We'd like them then to be produced in our case because, you know, these cases are separate, and if that's true then they should just reproduce them to us. There aren't that many.

THE COURT: How many?

MR. DRAYCOTT: There are a few categories of witness statements. There are six which we have confirmed were produced. These were voluntary statements that were taken for six individuals. They were turned over by the state of Texas to Abbott in May of 2006. I thought this was a frankly a dead issue based on my conversation with other Abbott counsel. They've absolutely got the witness statements. The other category of statements--

THE COURT: So can you agree to that, Mr. Daly, that in that category that you have them someplace?

MR. DALY: If counsel is certifying that we have that category through the Texas litigation--

THE COURT: Okay, moot then.

MR. DALY: --then I'll accept that, Your Honor.

MR. DRAYCOTT: I'll give Mr. Daly the names of the six individuals and if he, if for any reason Abbott doesn't have them they can come back to us.

THE COURT: All right. What about the other category?

MR. DRAYCOTT: The other category is there is, there are no, there are - the way the government can take statements is pursuant to a CID. We have no statements pursuant for a CID but our federal CID, that is our Civil Investigative Demand Statute places severe restrictions on what we can do by way of dissemination of material that we, the, for example, transcripts that we obtained. That's not really the issue because we don't have deposition transcripts. The state of Texas has its own False Claims Act under which it has a similar procedure for taking something called an examination under oath. There was some coordination between the state of Texas and the United States in which the United States has what are called EUO's--

THE COURT: How many people?

MR. DRAYCOTT: --examinations under oaths. Those, all the EUO's that were taken by the state of Texas that we've had access to have also been turned over to Abbott by the state of Texas. But as I explained to Abbott counsel was is that given that I'm completely unfamiliar with restrictions on dissemination of statements that were taken pursuant to a Texas law--

THE COURT: All right.

MR. DRAYCOTT: --I would just prefer because of any, because the state of Texas is better able to deal with restrictions on dissemination if there are any in their

statute, that they get them from the state of Texas which they've done. There's a complete production of the EUO's by the state of Texas to Abbott. They've got them all.

THE COURT: Okay. He thinks you have them, Mr. Daly. I want you to meet and confer to determine whether or not in fact you do have them if you don't figure out a way to produce them.

MR. DRAYCOTT: With respect to the other category which is the documents we have from a very - the documents that we've obtained during the investigation, we have been absolutely explicit from an early point in this case and indeed I've made an attachment to our opposition all the transmittal letters by which we have provided third party materials that we obtained and it's only being produced. There are some documents which haven't and those have been the subject of correspondence between myself and Abbott counsel where there is pricing information from other companies that were included on third party material. We've asked them to respond how we should deal with that.

THE COURT: All right. As to this category it sounds as if Abbott may actually have the documents. So sit down, find out if in fact you have them.

MR. DALY: Very well, Your Honor.

THE COURT: Next category?

MR. DALY: We would like, whether there's an EUO or a

formal statement, we would like a list of witnesses that the government interviewed which, you know, cause there may be people we want to go out and depose because it factored into their investigation.

THE COURT: Time period?

MR. DRAYCOTT: Your Honor, just if I could--

MR. DALY: Time period of their investigation, you know, from `95 to 2006--

THE COURT: All right.

MR. DALY: --when they unseal it.

MR. DRAYCOTT: Your Honor, on this category I think the most significant thing is when I asked Abbott counsel whether or not they would be willing to produce a list of people they interviewed once they learned of the government's investigation. I was told in no uncertain terms that that was privileged information. It would not be something that would be turned over by Abbott.

THE COURT: Well you can file your motion to compel if you--

MR. DRAYCOTT: Your Honor, my point is I don't believe that this is a proper - it is work product and what Abbott did--

THE COURT: The identities are work product?

MR. DRAYCOTT: Yes, I think so, Your Honor. This is not, this is just who we decided to interview. In the same way

- we're not suggesting that we're not going to turn over this category of information because Abbott won't. We think it's an improper--

THE COURT: What's your case?

MR. DRAYCOTT: --request.

THE COURT: What's your - give me a case that the identities are work product.

MR. DRAYCOTT: I think the ones cited in the brief all go to that issue which is that the fact - even the questions that are asked to that third party witness are protected work product.

THE COURT: We're not talking about the questions. We're talking about the identity.

MR. DRAYCOTT: Well, Your Honor, I think that what I'm asking Your Honor to consider is whether or not Abbott is, this is a credible argument that's not protected when Abbott is asserting exactly the same privilege with respect to that information when it's in Abbott's--

THE COURT: That's a tit for tat. That argument doesn't--

MR. DRAYCOTT: The question I'd respectfully ask Your Honor to ask Mr. Daly is, is he willing to produce to us precisely the same category of information that he is asking the government to produce?

THE COURT: No, I'm not going to ask him that. You

want to file a motion, if you want to file a request you can request and then we'll deal with it in turn.

MR. DRAYCOTT: And also, Your Honor--

THE COURT: I don't see any reason why - I don't see that the identities of the individuals--

MR. DRAYCOTT: Your Honor, it reflects - it is who we elect to go out and interview. It's a judgment about investigative and it turns us to who the, who may have information that's relevant. It is absolutely reflects a judgment about whether or not--

THE COURT: All right. I'll take another look at the cases but my inclination is that I will probably permit it. All right, Mr. Daly?

MR. DALY: Your Honor, in terms of pre-unsealing and investigation documents, the other thing we've asked for is the Relator when it files its complaint it files something, it gives to the government what's called a Relator's statement which under the False Claims Act is an assimilation of the facts, you know, as a matter of statute, of facts that upon which they base the complaint that they filed that they then give to the government with the complaint and say do you want to intervene. We have asked for the Relator's statement that was filed with the or given to the government in connection with the complaint that was filed against Abbott in 1995, and we've also asked and could even do these together, who within

the government got that and who got the Relator's complaint? So in other words, go back in time because this goes to knowledge for example because it's got all these facts about Abbott and others in there. It's got all these facts about the spread. We would like to have those facts because they're just facts, number one. And then we want to know to whom within the government was it distributed because that will tell us who got the stuff, who knew, who read it and we can go talk to them if necessary.

MR. DRAYCOTT: There is clear case law that the disclosure statement is a work product document. With respect to the facts therein this is a case in which relators have served initial disclosures and have answered discovery from Abbott. The disclosure statement is not simply a listing of facts, but it's an explanation as to the significance of those facts. It's a laying out of legal theory. It's tying them together. With respect to the facts that are in relator's possession that's turned over in the initial disclosures, it's subject to discovery which is ongoing in this case. The only thing that the disclosure statement adds to that is it presents the analysis of relator's counsels and lays out and ties up and is a presentation of a legal theory associated with that. It's clear work product. There's clear case law that it's protected and there's just no need to turn it over. It's also irrelevant. It doesn't - what Abbott has to defend against in

this case is the allegations in the complaint not what's in the disclosure statement. The disclosure statement is not part of the file. It's not by statute required to be served on in the court. It is just served on the Attorney General. So it's not a matter of them getting access to a document under seal because it's not under seal because it's not ever served with a court. So it's not a matter of disclosing something that's somehow part of the record in this case which any Court has ever seen. It's clearly a work product and there's just no relevance here and there's no need for it given that all the facts in relator's possession are, is evidence that can come out in the course of discovery.

THE COURT: All right.

MR. ANDERSON: Your Honor, if I may because this is also pending against the Relator, I'd also add that even Abbott's case law cited in their briefs recognizes that opinion work product is protected and that's only the portions of the disclosures that they don't have. All of the underlying facts have been produced that were part of the disclosure. So even their precedent that they are relying upon in their briefing is perfectly in tune with what the Relator has produced so far.

MR. DALY: Your Honor, we're not seeking opinion work product, I mean, they could redact this if need be. But I don't know how counsel can say that the facts upon which the complaint that was filed against us in 1995 are irrelevant.

They are not irrelevant and we don't know that it's been produced. The government has refused to give it to us. Maybe they're saying that bits and pieces of it have been produced in other context, I don't know. But in terms of our request to get the Relator's statement we've been completely foreclosed on that.

MR. DRAYCOTT: That's certainly not my position, Your Honor. The facts obviously they're entitled to. What is irrelevant is a theory that may be expressed, a legal opinion that's expressed in a disclosure statement that isn't part of the complaint is just not a legal theory that has to be defended against in this case.

THE COURT: All right, denied at this time.

MR. DALY: Your Honor, what about the two issues that I tied to that. One, who got it within the government and then who got the Ven-A-Care complaint that was filed in 1995? Would I be entitled to that?

THE COURT: What is your position on that?

MR. DRAYCOTT: Again, when we asked counsel for Abbott whether or not they were going - Abbott's been aware of this investigation from the first subpoena or first CID that was served and their position in terms of who they spoke to with the company about that investigation, when it occurred, who they went to in the company for information about the investigation, all of it according to Abbott is protected,

privileged information that they will not disclose. We agree with that position. What we disagree with strenuously is that somehow that these arguments only cut in one direction, that the same type of information when it's being held by Abbott is absolutely privileged and we agree it is privileged and it's also irrelevant. It's not, you know, who the government in its judgment within another branch of government or anywhere else elected to consult about a complaint is not the evidence in this case. And again, I want to make clear that we're not objecting to this because Abbott won't turn it over. I think Your Honor should be very skeptical on argument that this is somehow non-privileged information they're entitled to when precisely the same category of information they're asserting a privilege, won't turn it over and have said, you know, you don't get it.

THE COURT: All right, denied at this time. Anything else, Mr. Daly?

MR. DALY: Yes, Your Honor. The third - that was all the investigatory information. The final category is we've asked for the government to produce to us their evidence of false claims and false statements, kind of a basic aspect of the case. They've sued us under the False Claims Act. We've asked for them to identify the false statements we made, the alleged misrepresentations. What were they? When were they? What was wrong with them and what they should have been?

That's on the false statement side. On the false claims side under the False Claims Act, we've said, give us the false claims and we've even offered for them to do representative samples of both. In other words for each year, for each NDC, give us the misrepresentations or the representations, give us the alleged false claims and we'll start there because it is a large job.

One of the problems is that with Medicare for example I think the Court's heard mention that there are, you know, twenty some carriers that actually processed the claims for Medicare, they all have different AWP's that they use so the same drug Abbott's Vanco, for example, for one carrier might be reimbursed at $3 and for another carrier it's $15. Well, you know what, the fraud claim that they make is going to be different for each one of those. So we've asked them to come forward on that. On the Medicaid side as the Court is aware, the state has a slightly different and sometimes dramatically different way to reimburse these drugs. Some of them do a lot of AWP's, some of them do it on other reporting prices. Some of them put max or FUL's, maximum allowable costs or federal upper limit type numbers on them and so the government has sued us for all of the reimbursements by the states under Medicaid, and we think it's only fair that they have to come forward and show us what's false and show us what it should have been. And giving us, which they're in the process of doing, claims

information, doesn't cut it because all claims information is going to say that on such and such a date the state of Connecticut paid $25 for a vial of Vanco and it's going to be, you know, embedded in data. That's not going to tell us what's false, what it should have been or anything like that. So that's why we've offered at least preliminarily for them to do a representative sample of these items NDC by NDC, year by year.

THE COURT: Why not?

MR. DRAYCOTT: Absolutely they're entitled to the claim data as I think Mr. Daly just indicated. We are endeavoring to produce it. It is a time consuming process because of the manner in which this data is maintained. It's an antiquated system. We can't simply download the claims data to a hard drive. We have to - and we are now in consultation, that is the technical components of the two offices with Abbott trying to figure out the format in which the claims data can be produced. And there's two--

THE COURT: All right, so you're going to get the claims data.

MR. DRAYCOTT: Well, just to be--

MR. DALY: Right. They're working on it, correct.

MR. DRAYCOTT: --fair to Mr. Daly, I think there's two components of what he's talking about in terms of the damage analysis. The other part of it of course is what the,

it reflects the amounts that were paid and the claims that were paid with respect to the subject drugs at issue. The other component is of course what should have been paid by the just as Abbott has requested data information from the government. We in the same way have asked for sales and transaction data from Abbott. That is only now beginning to be forthcoming and there is a back and forth between other folks in my office and Abbott trying to, you know, they appear to have produced some electronic media with transactional data on it. We're now trying to figure out how to open it, how to read it, figuring out what kind of format it's in. Until all that is done and we can figure out what the transactional prices were which is then going to indicate the range of which the AWP actually should have been reported, you know, that is just a time consuming process and it requires information from Abbott in order for us to then be able to come up with a damage calculation which will then of course will be expressed in an expert report and is going to be I think the subject of a future round of discovery when it comes down to the expert phase of this litigation, at least the expert phase of the discovery process. And it's just too earlier for the government to, since we have not even been able to open yet the Abbott transactional data that we certainly can't provide that information yet.

MR. DALY: Just as I said, they are giving us the

claims data. My point about that is that our requests aren't about the claims data. Our request is about what's false. What's the false statement? What's the false claim? And we believe, and as I tried to explain, the data isn't going to answer that. The data is just going to give us a transaction price of 20 or 30 or 10 or 15 or $20, whatever it might be.

THE COURT: Well can you tell them how in what format you want this into?

MR. DALY: We have, Your Honor, in a letter. It's Exhibit 8 to our brief. We've asked them to give us by NDC by year for Medicaid, I'm sorry, Medicare, a statement of, you know, what's false, what's the false statement? What are you saying we misrepresented?

THE COURT: All right, why not?

MR. DRAYCOTT: Well we've indicated - we've indicated that it is the statement, the AWP statement through the compendia which again is this is a, in order to answer this question you have to understand the context in which these claims are made which is that the AWP is not a--

THE COURT: Trust me counsel, I understand.

MR. DRAYCOTT: --is not, if I've been presumptuous I apologize, Your Honor. But the reported price actually doesn't go to the government. It goes to the private compendia. And that is a transaction which the government is not a direct party and certainly that is an area of discovery that we're

taking against Abbott to get those statements. But that's going to be the core statement. With respect to the claim then that, the claim which is rendered false by that statement of an inflated AWP is the one that's paid for the beneficiary and that's the claims data we're trying to produce and we are in the process of producing. And I think the other part of this is, is again the falsity is--

THE COURT: All right, I'm going to wait until everything's produced. Denied without prejudice. You can renew it after you get a look at everything.

MR. DALY: I understand, Your Honor. Judge, that's all that there is on that motion.

THE COURT: All right. So the final motion is the motion for a protective order.

MR. DALY: Yes, Your Honor.

THE COURT: 4135.

MR. DALY: And that I believe is ours as well, Judge.

THE COURT: Yep.

MR. DALY: This is the argument concerning the government's notice for a deposition of Myles White--

THE COURT: Right.

MR. DALY: --who is the chief executive officer and the chairman of the board of my client, Abbott Laboratories. As the CEO and chairman, Mr. White is protected from potential harassment and abuse by the law that the Court's seen in the

briefs about what a party has to do in order to get an APEX deposition. The standard is clear that Mr. White must possess what the cases call unique personal knowledge of the subjects relevant to the case and the government must show that they have attempted less burdensome means to get the same information that they are seeking from the senior officer and we've cited a variety of cases for those two points.

As to the second point about trying to exhaust other means to get the information that they seek, the government hasn't done anything. They haven't said, they haven't argued the point. They say they don't have to. Well, in fact, under the case law they do because it makes sense to do it because, you know, the law is there for a reason. The law is there, you only get these people when you have a real need to do it. And so we didn't even confer about this. We attached the letter that the government wrote to us following our meet and confer. And this is the government's letter and they gave us four reasons why they say that they want to take Mr. White's deposition.

The first reason that they give in their letter is that Mr. White was the recipient of a litigation hold memo that went to about 70 other people. You know, your typical form, you know, there's litigation or there's an investigation, please maintain your files.

THE COURT: And has the letter been produced?

MR. DALY: Yes, Your Honor.

THE COURT: It has.

MR. DALY: But the fact that somebody got a litigation hold memo doesn't get you to take the deposition of the CEO and chairman of the board of a company. Unless the Court has any questions, I don't have anything left to say about that particular reason.

Reason number two, they say they want to inquire of Mr. White about briefings that he may have gotten about congressional inquiries or other investigations. Well, by defining it in that way about briefings is Mr. White is being told things by other people. By definition therefore he doesn't have unique personal knowledge of the subject that he's being briefed by others. So I think that topic is outside the scope of what they can do because it's not unique. It's by definition not unique. And we've filed also a short affidavit from Mr. White that confirms that.

The next reason given is that he was the addressee of a letter written by Congressman Stark several years ago. We've cited the cases that indicate that getting a letter in the course of a litigation or pre-litigation isn't something that's subjects an APEX executive to a deposition. Mr. White's affidavit addresses this by saying that he, you know, he's advised by others from time-to-time about, you know, pricing, marketing, issues like that relating to the price of drugs and

so I think we've addressed that in the sense that there's no indication that he has any unique knowledge about this and getting a letter from a congressman in and of itself is not reason to put somebody out for a deposition.

THE COURT: And has the letter been produced?

MR. DALY: Yes. The government sent it so they have it.

THE COURT: Yeah.

MR. DALY: It's out there. It's something that's been around for a number - I think it's a, I want to say it's a 2000 letter, Your Honor.

The final reason given is that they say that because Mr. White is the CEO he's responsible for everything and, therefore, he's responsible for Abbott's ethics and compliance policy and we want to talk to him because he's the CEO. If that were true the CEO being responsible ultimately for everything that goes on in a corporation they would be deposed everyday, all day in any case against these sorts of companies, and I don't think that that's reason enough.

I guess there was one more reason, Judge, and that is they wanted to ask him about the TAP settlement, that's in their letter which we attached. The Court's already ruled that out of the case in terms of discovery so I don't have anything more to say about that particular issue.

So we had a meet and confer. They gave us a letter,

it's attached. That's what they say they want to do. I don't think that those fall within any categories. They've done nothing on any of those categories to see if, you know, by written interrogatories or some other means, they can't get the information that they are seeking. They say they don't have to do that, that they can just go right to the top. I think the law is to the contrary.

THE COURT: All right, who's going to address that?

MR. NEIL: It's me, Your Honor, thank you. First of all you might have been wondering why the state of Texas was here, and my colleague Ray Winter from the state AG's office is here because they've also noticed the deposition of Mr. White in connection with their state case against Abbott. In fact if the Court grants this, I'm sorry, if the Court denies the motion and Mr. White is deposed there will be several plaintiffs and we'll obviously work with them to coordinate as necessary any deposition. But I don't want to be presumptuous. Let me argue the merits first.

As Your Honor's well aware you've already allowed the deposition of the CEO's in these cases. I think AstraZeneca attempted to get a protective order or didn't produce a CEO for a deposition. In the course of that there's a motion to compel by the MDL plaintiff's and you recognized that there are very important issues at stake in these cases and that corporate wide knowledge about how the company decided the price of

spreads is something that's very important and is relevant to this case. So you allowed the deposition of AstraZeneca's CEO when they didn't want to produce it. And it's my understanding also that you allowed the deposition of Bristol Myers Squibb or if you didn't allow it they didn't fight it necessarily. But CEO's have been deposed in these cases cause they're very significant cases. And in fact on the government's side we've allowed the deposition of three CMS administrators. CMS administrators are the equivalent of a CEO. They run obviously multi, hundreds of millions of dollars for federal program of health care. You know that. And that's cause there are important issues at stake and the government didn't try and block those depositions, although Abbott's, you know, if you try, it we tried to establish whether Abbott had shown the specific knowledge of Abbott's conduct and possession of those CMS people I think it'd be hard to do.

But more importantly let me go through the reasons. Mr. Daly discussed the reasons that we articulated for taking Mr. White's deposition and he didn't quite do them 100% justice.

In September of 2000 the House Ways and Means Committee was investigating Abbott at the same time the government was and news broke. And when the news broke of that Abbott's CEO, Mr. White, was questioned about it and he made various public statements. He talked about how if there are

abuses in the system, they need to be fixed, the AWP system. He talked about the structure of the regulations. He talked about the, you know, some of these allegations from the Ways and Means Committee in 2000 might have been politically motivated. He displayed a deep knowledge of the issues that were involved in terms of AWP pricing and the government reimbursement for drugs. That's not where the story ends obviously.

In October of 2000 Congressman Stark, the ranking democrat on the House Ways and Means Committee sent a letter to Mr. White. It wasn't just any letter, Your Honor. Congressman Stark basically went through and wrote a seven-page letter with 11 exhibits, it's an attachment to Abbott's motion for a protective order as well as our opposition, where he went through and systematically described what he thought was a fraud that was being committed against the United States, the same fraud that we're now suing Abbott on. He went through and he pointed out that none of this was sanctioned by any governmental entity whether it was the executive branch or the legislative branch. And he also pointed out the public health concerns that are arising from it cause one of the drugs that we sued on is Vancomycin and there's over prescription of Vancomycin which led to a real problem cause it's an antibiotic last resort. He wrote that letter in October of 2000. It's not everyday that a CEO gets a letter from a congressman

accusing the company of fraud. And I think the United States is entitled to ask Mr. White what he did when he received that letter.

Now in the briefings Abbott writes that, you know, there's no evidence that Mr. White got the letter. Well, if he didn't get the letter why did he put it in the affidavit he submitted to the Court? You know, there is a lot of factual background that we need to find out what happened when that letter was received. Now something did happen when that letter was received, Your Honor. Abbott ended the fraud. The fraudulent scheme in this case ends in May of 2001. And it ends in May of 2001 and there are documents that we finally received from Abbott that indicate that reason why the fraud ended in May of 2001 was in part because the public scrutiny that was coming from Congress and the press related to Abbott's pricing policies could not justify, was not justified by the amount of profit the company is earning. And there's a memorandum that discusses it that we have with our materials that we submitted in our opposition. But there's a direct link between the letter from Congressman Stark to Mr. White to a major corporate decision to end the way that Abbott was pricing its drugs in our view ends the fraudulent scheme here.

In some respects Mr. White may very well be the hero of the story for us in terms of being the one who decided that as a corporate matter I'm the CEO, I'm tired of Congress coming

in and accusing us of fraud, we need to change what's going on here. And they did ultimately change it. So he's at the core of the end, the end of the fraud in this case. And there's nothing in the affidavit that he submitted that indicates otherwise. The only thing you have in the affidavit is a know nothing affidavit, I don't know anything, what I knew I knew from secondary sources. Well as Your Honor knows from the *Traveler's* decision in this district where Judge Collings said that these kinds of know nothing affidavits, you know, are subject to discovery, are subject to questioning because if they didn't know anything it could be telling. If Mr. White got a letter from a congressmen accusing him of fraud and throws it in the trash can well that actually goes to the company's scienter cause under the False Claims Act if a company CEO is deliberately ignorant when put on notice of a fraud that's relevant to scienter. And based on the evidentiary record that we've seen he didn't just throw it away. Someone, Mr. White, and we'll find out from Mr. White whether he was the hero of the story, ended the fraud and that's what we want to get to the bottom of. Thank you, Your Honor.

THE COURT: Briefly, Mr. Daly.

MR. DALY: Yes, Your Honor.

THE COURT: I'll get to you.

THE COURT: Your Honor, the Stark letter as the

affidavits to the attached state was never responded to first of all. Second of all, as Mr. White says in his affidavit, you know, events surrounding that would have been discussions with counsel and they would be privileged. One of the things that you don't hear in the argument from the government is that any suggestion that this individual's knowledge is unique, if they want to know, and they do want to know and they have been asking questions of others, you know, what happened? Did you get the Stark letter? You know, what changes did you make, why did you make them, et cetera, et cetera, et cetera, go ahead and ask away. But what they have to do to get Mr. White is show that there's something unique about his knowledge because the cases make clear that at most I think my brother, Mr. Gobena, his argument would suggest that Mr. White might have discoverable information. The cases make clear that that's not enough. You need to have unique personal knowledge that you can't get from anybody else and we've heard nothing that remotely suggests that there's something that they can only get from Mr. White.

THE COURT: What's your response to that?

MR. NEIL: My response is that a letter was sent from a congress person to Mr. White, the CEO of the company. The only person who's going to know whether he received it, how he reacted to it, the way he directed to do firsthand is going to be Mr. White. It's not going to be anyone else. I don't think

the United States should be required to go and get hearsay testimony--

THE COURT: All right, you can ask him that in written deposition questions, three written deposition questions, and then you can renew this motion.

MR. NEIL: Okay.

MR. GOBENA: I take it then, Your Honor, that you wouldn't want to hear from me on this?

THE COURT: Well, if you'd like to speak I'll always let you speak but I think that's going to be my approach. Unless you have some further information beyond what's in your papers as to his specific knowledge.

MR. GOBENA: I do, Your Honor, I'll be brief.

THE COURT: All right then.

MR. GOBENA: First, I would ask that the Court review the *Travelers'* opinion that came out of this district.

THE COURT: I know the *Travelers'* opinion.

MR. GOBENA: And I think it sets forth a standard that is slightly different in significant ways than my brother, Mr. Daly, set forth. I think in pertinent part it does not state that this knowledge has to be at the level that he requires, but furthermore I want to say specifically that I personally have taken the deposition of several witnesses and this memo where pricing changes are instituted by Abbott and explicitly mention the Stark letter, the 2000 Stark letter

addressed to Myles White individually, that is specifically mentioned in the memo as a part of the reason why these changes are being instituted. That has been marked as Exhibit 940. We have asked several witnesses if they have seen that. Do they know anything about that memo and they all say no.

Now, the reason why I mention that is because this letter from Congressman Stark went to Myles White. However it was delegated by Mr. White a response was provided. The response was not in a written response to Congressman Stark. A response was in the form of a change in their price reporting and price setting conduct. That I think is very pertinent. And the *Travelers'* opinion says that when you have a case that involves motive and intent getting testimony from the APEX individual is critical because ultimately that has far more probative value about what the corporation intended, what the corporation motives were.

THE COURT: Well, I'm not saying that you're not going to be permitted to have that deposition, but what I'm saying is as a preliminary matter I will allow three written deposition questions on this limited area, and you can renew the motion after that if you're not satisfied with the information you get and you think you need then to have this live deposition. So it's a start.

MR. GRABINO: I understand. Thank you, Your Honor.

THE COURT: All right. So as to docket entry 3959,

the motion on deliberative process, I'm going to take that under advisement and give you a short ruling. As to 4135, allowed in part and denied in part as set froth in the record in open court. And as to 4202, it's denied except to the extent that you may file three written deposition questions as set forth specifically in court.

All right, hearing nothing else - all right and I appreciate counsel accommodating the change in the Court's schedule.

MR. DALY: Thank you very much, Judge.

MR. NEIL: Thank you, Your Honor.

THE COURT: You're welcome.

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CERTIFICATION

I, Maryann V. Young, court approved transcriber, certify that the foregoing is a correct transcript from the official digital sound recording of the proceedings in the above-entitled matter.

/s/ Maryann V. Young July 30, 2007